HEALTH ACT

Promulgated, SG No. 70/10.08.2004, effective 1.01.2005, supplemented, SG No. 46/3.06.2005, amended and supplemented, SG No. 76/20.09.2005, effective 1.01.2007, SG No. 85/25.10.2005, effective 25.10.2005, amended, SG No. 88/4.11.2005, amended and supplemented, SG No. 94/25.11.2005, effective 25.11.2005, amended, SG No. 103/23.12.2005, amended and supplemented, SG No. 18/28.02.2006, effective 1.01.2007, amended, SG No. 30/11.04.2006, effective 12.07.2006, SG No. 34/25.04.2006, effective 1.01.2008 (*)(**), amended and supplemented, SG No. 59/21.07.2006, effective 1.01.2007, SG No. 71/1.09.2006, effective 1.01.2007, SG No. 75/12.09.2006, (*) amended, SG No. 80/3.10.2006, effective 3.10.2006, supplemented, SG No. 81/6.10.2006, amended, SG No. 95/24.11.2006, effective 24.11.2006, SG No. 102/19.12.2006, SG No. 31/13.04.2007, effective 13.04.2007, SG No. 41/22.05.2007, SG No. 46/12.06.2007, (*) amended, SG No. 53/30.06.2007, effective 30.06.2007, amended and supplemented, SG No. 59/20.07.2007, effective 26.05.2007, amended, SG No. 82/12.10.2007, amended and supplemented, SG No. 95/20.11.2007, effective 1.01.2008, amended, SG No. 13/8.02.2008, effective 8.02.2008, SG No. 102/28.11.2008, amended and supplemented, SG No. 110/30.12.2008, effective 1.01.2009, SG No. 36/15.05.2009, SG No. 41/2.06.2009, effective 2.06.2009, amended, SG No. 74/15.09.2009, effective 15.09.2009, SG No. 82/16.10.2009, effective 16.10.2009, SG No. 93/24.11.2009, effective 25.12.2009, SG No. 99/15.12.2009, effective 1.01.2010, amended and supplemented, SG No. 101/18.12.2009, effective 18.12.2009, supplemented, SG No. 41/1.06.2010, amended and supplemented, SG No. 42/4.06.2010, effective 2.06.2010, amended, SG No. 50/2.07.2010, amended and supplemented, SG No. 59/31.07.2010, effective 31.07.2010, amended, SG No. 62/10.08.2010, effective 10.08.2010, amended and supplemented, SG No. 98/14.12.2010, effective 1.01.2011, amended, SG No. 100/21.12.2010, effective 1.01.2012, amended and supplemented, SG No. 8/25.01.2011, effective 25.01.2011, supplemented, SG No. 9/28.01.2011, SG No. 45/14.06.2011, effective 14.06.2011, SG No. 60/5.08.2011, effective 5.08.2011, amended, SG No. 38/18.05.2012, effective 1.07.2012, amended and supplemented, SG No. 40/29.05.2012, SG No. 54/17.07.2012, supplemented, SG No. 60/7.08.2012, effective 7.08.2012, amended, SG No. 82/26.10.2012, effective 26.11.2012, SG No. 101/18.12.2012, effective 1.01.2013, SG No. 102/21.12.2012, effective 21.12.2012, SG No. 15/15.02.2013, effective 1.01.2014, SG No. 30/26.03.2013, effective 26.03.2013, SG No. 66/26.07.2013, effective 26.07.2013, SG No. 68/2.08.2013, effective 2.08.2013, supplemented, SG No. 99/15.11.2013, amended, SG No. 104/3.12.2013, effective 4.01.2014, amended and supplemented, SG No. 106/10.12.2013, effective 1.01.2014, SG No. 1/3.01.2014, effective 3.01.2014, amended, SG No. 98/28.11.2014, effective 28.11.2014, supplemented, SG No. 107/24.12.2014, effective 1.01.2015, amended, SG No. 9/3.02.2015, effective 3.02.2015, supplemented, SG No. 72/18.09.2015, SG No. 80/16.10.2015, effective 16.10.2015, SG No. 102/29.12.2015, effective 1.01.2016, SG No. 17/1.03.2016, effective 1.03.2016, amended and supplemented, SG No. 27/5.04.2016, supplemented, SG No. 98/9.12.2016, effective 1.01.2017, amended, SG No. 103/27.12.2016, SG No. 58/18.07.2017, effective 18.07.2017, SG No. 85/24.10.2017, amended and supplemented, SG No. 102/22.12.2017, effective 1.01.2018, SG No. 18/27.02.2018, effective 27.02.2018, supplemented, SG No. 77/18.09.2018, effective 1.01.2019, amended and supplemented, SG No. 91/2.11.2018, SG No. 98/27.11.2018, effective 27.11.2018, SG No. 102/11.12.2018, effective 1.01.2019, amended, SG No. 24/22.03.2019, effective 1.07.2020 (*), amended and supplemented, SG No. 58/23.07.2019, supplemented, SG No. 99/17.12.2019, effective 17.12.2019, amended, SG No. 101/27.12.2019, amended and supplemented, SG No. 23/14.03.2020, effective 14.03.2020, SG No. 28/24.03.2020, effective 13.03.2020, amended, SG No. 34/9.04.2020, effective 9.04.2020, amended and supplemented, SG No. 44/13.05.2020, effective 14.05.2020, amended, SG No. 67/28.07.2020, amended and supplemented, SG No. 103/4.12.2020, effective 4.12.2020, SG No. 105/11.12.2020, effective 11.12.2020, SG No. 110/29.12.2020, effective 30.06.2021, supplemented, SG No. 21/12.03.2021, effective 12.03.2021, amended, SG No. 8/28.01.2022, effective 1.01.2022, SG No. 17/1.03.2022, effective 1.04.2022, amended and supplemented, SG No. 18/4.03.2022, effective 4.03.2022, SG No. 32/26.04.2022, effective 26.04.2022, supplemented, SG No. 41/3.06.2022, effective 3.06.2022, amended, SG No. 58/23.07.2022, effective 1.01.2023, amended and supplemented, SG No. 62/5.08.2022, effective 5.08.2022; amended with Decision No. 14/17.11.2022 of the Constitutional Court of Republic of Bulgaria - SG No. 94/25.11.2022; amended, SG No. 102/23.12.2022, effective 1.01.2023, SG No. 104/30.12.2022, effective 1.01.2023, amended and supplemented, SG No. 8/25.01.2023, supplemented, SG No. 66/1.08.2023, effective 1.01.2023, amended, SG No. 80/19.09.2023, supplemented, SG No. 86/13.10.2023, effective 13.10.2023, amended, SG No. 96/17.11.2023, effective 17.11.2023

*Note: An update of the English text of this Act is being prepared following the amendments in SG No. 102/8.12.2023, effective 12.12.2023, SG No. 35/19.04.2024, effective 19.04.2024, SG No. 39/1.05.2024, effective 1.05.2024

(*) effective 1.07.2007 - amended, SG No. 80/3.10.2006, effective 3.10.2006

(**) effective 1.01.2008 - amended, SG No. 53/30.06.2007, effective 30.06.2007

Chapter One
NATIONAL HEALTHCARE SYSTEM
Section I
General Provisions

Article 1

This Act shall regulate the social relations concerning the protection of the citizens' health.

Article 2

The protection of the citizens' health as a condition of full physical, mental and social wellbeing is a national priority and it shall be guaranteed by the government through the application of the following principles:

1. equality in the use of health services;
2. ensuring accessible and high-quality healthcare, giving priority to children, pregnant women and mothers of children aged up to one year;
3. priority of health promotion and the integrated disease prevention;
4. prevention and reduction of the health risk to citizens as a result of adverse effects of environmental factors;
5. special health protection of children, pregnant women, mothers of children aged up to one year and people with physical and mental disabilities;
6. participation of the government in the financing of activities aimed at protecting the health of citizens.

Article 3

(1) The government health policy shall be guided and implemented by the Council of Ministers.

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

(3) (Supplemented, SG No. 32/2022, effective 26.04.2022) The Council of Ministers, at the proposal of the Minister of Health, shall adopt national health programmes and the national plans.

(4) (Amended, SG No. 32/2022, effective 26.04.2022) The National Health Strategy, the national health programmes and the national plans shall build on an assessment of the health condition and health needs of the citizens, the health and demographic trends, as well as the resource capacities of the national healthcare system.

(5) (Amended, SG No. 15/2013, effective 1.01.2014, supplemented, SG No. 32/2022, effective 26.04.2022) National health programmes and the national plans shall be financed from the state budget as separate expenditures from the budget of the Ministry of Health and may be supported by other financial sources.

Article 4

(Amended, SG No. 31/2007)

The national healthcare system shall include the medical treatment facilities under the Medical Treatment Facilities Act, the healthcare facilities under this Act and the Medicinal Products in Human Medicine Act, as well as the central, local and non-governmental bodies and institutions for organisation, management and control of health-protection and building activities.

Section II
Managing Bodies of the National Healthcare System

Article 5

(1) The Minister of Health shall guide the national healthcare system and exercise control over the activities related to:

1. the protection of the citizens' health and the state health control;
2. the provision of urgent medical aid, transfusion haematology, psychiatric aid at specialised facilities, medical and social care for children aged up to three years, transplantations and health information;

3. the provision and sustainable development of health activities at medical and healthcare facilities;
4. medical expert activities.
(2) The Minister of Health shall submit to the National Assembly an annual report on the condition of the citizens' health and the implementation of the National Health Strategy within three months before the beginning of the fiscal year.
(3) (Amended, SG No. 15/2013, effective 1.01.2014) The Minister of Health shall approve the allocation of the state budget transfers for the activities under this Act by programmes, except for the activities under Paragraph (1), Items 1 and 2.
(4) (Amended, SG No. 88/2005, SG No. 93/2009, effective 25.12.2009) The Minister of Health shall provide methodological guidance and control of the medical activities of the medical treatment facilities set up at the Council of Ministers, the Ministry of Defence, the Ministry of Interior, the Ministry of Justice and the Ministry of Transport, Information Technology and Communications.
(5) The Minister of Health shall exercise also other powers prescribed by law or a secondary legislative act of the Council of Ministers.

Article 6

(1) The Supreme Medical Council shall be set up at the Minister of Health.
(2) (Supplemented, SG No. 46/2005, SG No. 75/2006, SG No. 91/2018) The Supreme Medical Council shall include five representatives designated by the Minister of Health, five representatives of the Bulgarian Medical Association, three representatives of the Bulgarian Dental Association, three representatives of the Union of Pharmacists in Bulgaria, three representatives of the National Health Insurance Fund (NHIF), one representative of the Bulgarian Association of Health Care Professionals, one representative of the Bulgarian Association of Dental Technicians and a representative of the National Association of Municipalities, each higher medical school and the Bulgarian Red Cross each. The Minister of Health shall serve as the Chairperson of the Council in a non-voting capacity.
(3) The Supreme Medical Council shall be an advisory body, discussing and giving opinions on:
1. the priorities of the National Health Strategy;
2. ethical issues of medicine and biomedicine;
3. bills and drafts of secondary legislative acts of the Council of Ministers in the field of healthcare and within the competence of the Minister of Health;
4. the report of the Minister of Health under Article 5 (2);
5. the draft of the annual health budget;
6. the research priorities in the field of medicine and dental medicine;
7. the annual admission of students and postgraduates in the professional area of health and the criteria for selecting facilities to conduct undergraduate and postgraduate training under Articles 91 and 92 of the Medical Treatment Facilities Act;
8. the types of specialties in the professional area of health.
(4) The organisation and activities of the Supreme Medical Council shall be regulated in Rules drafted by the Supreme Medical Council and approved by the Minister of Health.

Article 6a

(New, SG No. 41/2009, effective 2.06.2009)
(1) (Amended, SG No. 102/2018, effective 1.01.2019) The Minister of Health shall appoint by an order:
1. expert councils in medical specialties or individual medical activities;
2. executive consulting experts in medical specialties.
(2) (Amended, SG No. 102/2018, effective 1.01.2019) The expert councils referred to in Item 1 of Paragraph (1) shall consist of medical specialists in the respective fields of medicine and/or in the healthcare system and shall provide consultations and opinions on questions assigned to them by the Minister of Health.

(3) (Amended, SG No. 98/2010, effective 14.12.2010) Executive consulting experts shall consult medical treatment facilities for in-patient health care, mental health centres, comprehensive oncology centres, and skin and venereal diseases centres in providing medical care.
(4) The funding for the activities referred to in Paragraph (2) shall be provided from the Ministry of Health's budget for the respective calendar year, and that for the activities referred to in Paragraph (3), from the relevant medical treatment facilities.
(5) (Amended, SG No. 102/2018, effective 1.01.2019) The terms and procedures for the funding, organisation and execution of activities of the expert boards and the republican consulting experts shall be laid down in an ordinance of the Minister of Health.

Article 7

(1) (Amended, SG No. 98/2010, effective 1.01.2011) The government health policy within the territory of administrative regions shall be implemented and organised by the regional health inspectorate.
(2) (Amended, SG No. 98/2010, effective 1.01.2011) For the purposes of organising healthcare within municipalities, the respective municipal council may set up a healthcare service within the framework of the municipal administration. The service shall operate under the methodological guidance of the regional health inspectorate.

Article 8

(1) (Amended, SG No. 98/2010, effective 1.01.2011, SG No. 15/2013, effective 1.01.2014) Regional health inspectorates shall be budget-supported legal entities under the Minister of Health seated in the community which is the administrative centre of the region.
(2) (Amended, SG No. 98/2010, effective 1.01.2011) Regional health inspectorates shall be established, re-organised and closed by the Council of Ministers.

Article 9

(Amended, SG No. 98/2010, effective 1.01.2011)
(1) A regional health inspectorate (RHI) shall be managed and represented by a director assisted by a deputy director.
(2) RHI directors shall be appointed on the basis of a competition held by the Minister of Health as per the procedure laid down in the Labour Code.
(3) A RHI director may be a person who holds the academic degree of Master of Medicine and who has undergone recognised medical specialist training and obtained a qualification in health management, with three-year length of service following the specialist training.
(4) Any RHI director shall be subject to evaluation, once every three years, by a commission appointed by the Minister of Health. The evaluation procedure shall be laid down in the regulations under Article 10(3).
(5) The Minister of Health may terminate the employment contract of any RHI director who has received a negative evaluation by serving a prior notice pursuant to Article 328, (1), Item 5 of the Labour Code.
(6) RHI deputy directors shall be appointed on the basis of a competition held by the respective RHI director as per the procedure laid down in the Labour Code.
(7) A RHI deputy director may be a person who holds the academic degree of Master of Medicine and who has undergone recognised medical specialist training and obtained a qualification in health management.

Article 10

(Amended and supplemented, SG No. 41/2009, effective 2.06.2009, amended, SG No. 98/2010, effective 1.01.2011)
(1) Within the territory of the respective regions, the regional health inspectorates shall carry out activities related to:
1. state health control;

2. control in respect of the registration and healthcare activities provided by the medical treatment and health facilities;
3. inspections regarding compliance with requirements under Article 40(4) and Article 47(4) of the Medical Treatment Facilities Act;
4. planning, organisation, supervision and control of medical expert activities;
5. health promotion and integrated disease prevention;
6. collection, registration, processing, storage, analysis and provision of health information for the needs of the national healthcare system;
7. monitoring of environmental factors, as well as activities of public health importance;
8. analyses, assessments and forecasts concerning health and demographic processes at the regional level;
9. laboratory analyses and testing;
10. development and implementation of regional health programmes and projects;
11. coordination and implementation of national and international health programmes and projects.
12. methodological, consulting and expert assistance;
13. post-graduate practicum in the field of public health protection;
14. inspections upon citizen alerts and complaints related to public health protection;
15. planning and organisation of healthcare activities in the event of natural calamities, accidents or disasters, as well as creation of wartime plan for the territory of the respective region.
(2) Regional health inspectorates, together with the professional organisations, shall examine the needs for medical and non-medical specialists with higher education and propose to the Minister of Health the number of postgraduate places in different specialties.
(3) The names and number of directorates within the general and specialised administration of each RHI, including the functions thereof and the number of staff, shall be set out in regulations issued by the Minister of Health.
(4) By the regulations under Paragraph 3, the Minister of Health may entrust certain RHIs with the implementation of activities which are to cover the territory of several regions, or the whole territory of Bulgaria.

Article 10a

(New, SG No. 41/2009, effective 1.01.2009, amended, SG No. 98/2010, effective 1.01.2011)
(1) The revenues of RHIs shall be formed by:
1. (amended, SG No. 15/2013, effective 1.01.2014) state budget subsidy;
2. their own activities;
(2) Regional health inspectorates shall administer the revenues referred to in Paragraph (1), Item 2, formed by:
1. state fees;
2. fines and pecuniary sanctions imposed by enforced penalty orders issued by RHI directors and having been credited to the respective RHI accounts;
3. other sources.
(3) The funds referred to in Paragraph (1), Item 2 shall be spent on:
1. exercising of control activities;
2. non-infectious disease prevention, as well as infectious disease prevention and monitoring;
3. creating, maintaining and keeping the registers provided for in this Act and in other statutory instruments which have been assigned to RHIs;
4. laboratory analyses and testing;
5. participation in national and international testing;
6. accreditation, as well as maintaining existing accreditations of RHI laboratories;
7. dissemination of information and scientific materials;
8. (repealed, SG No. 38/2012, effective 1.07.2012);
9. (repealed, SG No. 38/2012, effective 1.07.2012).

Section III
State Health Control

Article 11
(Amended, SG No. 98/2010, effective 1.01.2011)
State health control shall be exercised in order to protect public health within the territory of the Republic of Bulgaria by implementing the activities under Article 15.

Article 12
(1) (Amended, SG No. 98/2010, effective 1.01.2011) The state health control authorities shall include the Chief State Health Inspector of the Republic of Bulgaria, the regional health inspectorates and the National Centre for Radiobiology and Radiation Protection (NCRRP).
(2) (Amended, SG No. 59/2006, SG No. 98/2010, effective 1.01.2011) State health control shall be performed by state health inspectors at the Ministry of Health, RHIs and the NCRRP. The state health inspectors at the Ministry of Health and RHIs shall be civil servants.
(3) State health inspectors may not engage in any form of activity which is subject to state health control.

Article 13
(1) The Chief State Health Inspector shall be appointed by the Prime Minister at the proposal of the Minister of Health.
(2) The powers of the Chief State Health Inspector in his/her absence from the country or during his/her legitimate leave shall be exercised by a deputy appointed in each individual case by the Minister of Health with an order in writing from among the employees in the administration of the Ministry of Health.
(3) The activities of the Chief State Health Inspector shall be supported by the administration of the Ministry of Health.

Article 14
(1) The Chief State Health Inspector shall organise and manage:
1. (supplemented, SG No. 98/2010, effective 1.01.2011) the state health control under Article 15;
2. the activities related to health promotion and the integrated disease prevention;
3. (repealed, SG No. 98/2010, effective 1.01.2011);
4. (repealed, SG No. 98/2010, effective 1.01.2011);
5. preventive and anti-epidemic activities in the event of natural calamities, accidents and disasters.
(2) (Supplemented, SG No. 98/2010, effective 1.01.2011) The Chief State Health Inspector shall provide methodological guidance and supervision of the institutional health control units at the Ministry of Justice, Ministry of Transport, Information Technology and Communications, Ministry of Defence and the Ministry of Interior.

Article 15
(Amended, SG No. 98/2010, effective 1.01.2011)
(1) Regional health inspectorates shall exercise state health control by implementing activities related to:
1. exercising control in respect of the fulfilment and compliance with health requirements, as laid down in statutory instruments, concerning public use facilities under § 1, item 9 of the Additional Provision;
2. exercising control in respect of the fulfilment and compliance with health requirements, as laid down in statutory instruments, concerning products and goods of importance to human health under § 1, item 10 of the Additional Provision;
3. exercising control in respect of the fulfilment and compliance with health requirements, as laid down in statutory instruments, concerning activities of importance to human health under § 1, item 11 of the Additional Provision;

4. exercising control in respect of the fulfilment and compliance with health requirements, as laid down in statutory instruments, concerning environmental factors under § 1, item 12 of the Additional Provision;
5. monitoring infectious diseases;
6. exercising control in respect of the compliance with prohibitions and limitations laid down in statutory instruments as to the advertising and sale of alcoholic beverages;
7. exercising control in respect of the compliance with prohibitions and limitations laid down in statutory instruments as to smoking.
(2) The state health control in respect of the compliance with requirements aimed at protecting people against the effect of ionizing radiation shall be implemented by RHIs designated by the Minster of Health and by the NCRRP.

Article 16
(Repealed, SG No. 98/2010, effective 1.01.2011).

Article 17
(Supplemented, SG No. 41/2009, effective 2.06.2009, repealed, SG No. 98/2010, effective 1.01.2011).

Article 18
(Amended, SG No. 41/2009, effective 1.01.2009, repealed, SG No. 98/2010, effective 1.01.2011).

Article 18a
(New, SG No. 41/2009, effective 1.01.2009, repealed, SG No. 98/2010, effective 1.01.2011).

Article 19
(1) The state health control shall be performed systematically without any prior notice and especially on the occasion of alerts from citizens, central and local government bodies and organisations, or where other information on the occurrence of accidents is available.
(2) In the course of the implementation of the state health control, state health inspectors shall be entitled to:
1. free access to the facilities, products, goods, activities and persons subject to control;
2. demand information and documents and receive copies thereof on paper and/or electronic carrier;
3. take samples for laboratory analysis in the quantities needed for the testing;
4. commission examinations and tests for assess the health condition of the persons under Article 34, Paragraph (3);
5. prescribe the removal from work of persons who are ill or carriers of an infection and constitute a threat to the health of the people around them;
6. prescribe mandatory hygienic and anti-epidemic measures, specifying time limits for their implementation;
7. (new, SG No. 98/2010, effective 1.01.2011) decommission public facilities or parts thereof, or the relevant operations, in the circumstances under Article 38(3), immediately notifying the RHI director;
8. (new, SG No. 98/2010, effective 1.01.2011) suspend the marketing of products and goods of importance to human health in the circumstances under Article 39(1)(1);
9. (renumbered from Item 7, SG No. 98/2010, effective 1.01.2011) place certification signs in the cases under Arts. 38 and 39;
10. (renumbered from Item 8, SG No. 98/2010, effective 1.01.2011) to draw up acts establishing the presence of administrative violations;
11. (new, SG No. 41/2009, effective 2.06.2009, renumbered from Item 9, SG No. 98/2010, effective 1.01.2011) propose that the bodies of the National Construction Control Directorate issue a decision to refuse the acceptance of community projects while putting development projects in the Republic of Bulgaria into operation, where serious violations of the norms and requirements laid down in an enactment have been found;

12. (new, SG No. 41/2009, effective 2.06.2009, renumbered from Item 10, SG No. 98/2010, effective 1.01.2011) issue sanitary opinions on the conformity of community projects, products, goods and activities of importance to human health and of maximum admissible levels of environmental factors with health requirements;
13. (renumbered from Item 9, SG No. 41/2009, effective 2.06.2009, renumbered from Item 11, SG No. 98/2010, effective 1.01.2011) propose coercive administrative measures as provided by law.
(3) (Amended, SG No. 98/2010, effective 1.01.2011) The coercive administrative measures shall be imposed by order of the RHI directors.
(4) The terms and conditions for exercising state health control shall be set out in an ordinance issued by the Minister of Health.

Article 19a

(New, SG No. 41/2009, effective 2.06.2009)
(1) Samples taken from products and goods of importance to human health and environmental factors for the purposes of state health controls shall be analysed in laboratories specified in an order to be issued by the Minister of Health.
(2) The laboratories referred to in Paragraph (1) must be accredited in conformity with the requirements of BDS EN ISO/IEC 17025 and/or of BDS EN ISO/ IEC 17020 and the accreditation of testing laboratories under BDS EN ISO/IEC 17025 should cover certain tests or groups of tests.
(3) The Minister of Health may by an order designate laboratories for analysis which have not been accredited in pursuance of Paragraph (2) for a certain period of time provided that:
1. these laboratories have initiated the necessary accreditation procedures;
2. there is evidence that these laboratories apply systems and procedures for control and testing that ensure quality laboratory practices during the performance of analyses for the purposes of the state health controls.

Article 20

(Amended, SG No. 41/2009, effective 1.01.2009, SG No. 98/2010, effective 1.01.2011)
The voluntary payment of fines and pecuniary sanctions imposed through enforceable penalty orders issued by the state health control authorities may be made at the Ministry of Health or the respective RHI.

Section IV
Healthcare Facilities

Article 21

(1) Healthcare facilities shall be structures of the national healthcare system, where medical and non-medical specialists exercise activities for the protection and promotion of the health of citizens.
(2) Within the meaning of this Act, healthcare facilities shall be:
1. the national centres for public health affairs;
2. the National Medical Expert Panel (NMEP);
3. health offices under Article 26;
4. (new, SG No. 81/2006) the opticians' shops referred to in Article 26a.
(3) (Amended, SG No. 31/2007) Pharmacies shall be healthcare facilities with status and activities set out in the Medicinal Products in Human Medicine Act.

Article 22

(1) (Amended, SG No. 15/2013, effective 1.01.2014) National centres for public health affairs shall be budget-supported legal entities under the Minister of Health, which shall be opened, re-organised and closed by the Council of Ministers at the proposal of the Minister of Health.
(2) National centres for public health affairs shall be managed and represented by a director appointed on the basis of a competition announced by the Minister of Health.
(3) The directors of the national centres for public health affairs shall be subject to evaluation by a commission appointed by the Minister of Health once in three years. The evaluation procedure shall

be laid down in the regulations for the structure and activity of the respective national centre for public health affairs.
(4) The Minister of Health may terminate the employment contract of a director of a national centre for public health affairs who has received a negative evaluation with a notice pursuant to Article 328, Paragraph (1), Item 5 of the Labour Code.

Article 23

(1) National centres for public health affairs shall carry out activities related to:
1. the preparation of studies, assessments, expert opinions and reports, analyses and forecasts in the field of the protection of public health;
2. the prevention, reduction and liquidation of epidemics of infectious diseases;
3. the organisation, management and coordination of medical aid in the event of natural calamities, accidents and disasters within the territory of the Republic of Bulgaria;
4. the assessment of the risk and adverse effect of environmental factors on the individual, family and public health;
5. laboratory tests and expert reports;
6. (supplemented, SG No. 98/2010, effective 1.01.2011) protection of people against the effects of ionizing and non-ionizing radiation;
7. the health promotion and the integrated disease prevention;
8. (amended, SG No. 98/2010, effective 1.01.2011) the expert and advisory support to RHIs;
9. the expert, advisory and methodological support to medical and healthcare facilities;
10. the planning and conduct of basic and applied research;
11. the state health control in the cases provided by law;
12. educational activities;
13. (new, SG No. 98/2010, effective 1.01.2011) collecting, summarising and analysing information concerning the operations of the RHIs.
(2) The structure and activities of individual national centres for public health affairs shall be set out in regulations issued by the Minister of Health.

Article 24

(1) The revenues of national centres for public health affairs shall be generated from:
1. (amended, SG No. 15/2013, effective 1.01.2014) state budget subsidy;
2. gifts and inheritance;
3. other budget revenues from:
(a) (amended, SG No. 98/2010, effective 1.01.2011) state fees;
(b) research and expert activities;
(c) postgraduate tuition fees.
(2) (Repealed, SG No. 38/2012, effective 1.07.2012).

Article 25

(1) (Amended, SG No. 15/2013, effective 1.01.2014) The National Expert Medical Commission shall be a budget-supported legal person under the Minister of Health seated in Sofia.
(2) The National Expert Medical Commission shall be managed and represented by a director appointed on the basis of a competition announced by the Minister of Health.
(3) (New, SG No. 41/2009, effective 2.06.2009) The NMEP Director shall be attested every three years by a committee appointed by the Minister of Health. The attestation procedure shall be laid down in the rules of procedure provided for in Article 109.
(4) (New, SG No. 41/2009, effective 2.06.2009) In the case of negative attestation, the Minister of Health may dismiss the NMEP Director with advance notice as provided for in Article 328 (1), Item 5 of the Labour Code.
(5) (Renumbered from Paragraph 3, SG No. 41/2009, effective 2.06.2009) The National Expert Medical Commission shall perform expert, controlling, methodological and advisory activities in the expert assessment of the capability for work.

Article 26

(1) (Amended, SG No. 41/2009, effective 2.06.2009) Healthcare offices may be established at:

1. kindergartens and schools;

2. (repealed, SG No. 95/2007);

3. (amended, SG No. 95/2007, SG No. 41/2009, effective 2.06.2009, SG No. 24/2019, effective 1.07.2020 - amended, SG No. 101/2019) social and integrated health and social services for residential care for more than 20 users and at social services for providing shelter.

(2) (Amended, SG No. 103/2005, supplemented, SG No. 95/2007, amended, SG No. 41/2009, effective 2.06.2009, amended, SG No. 74/2009, SG No. 50/2010, SG No. 68/2013, effective 2.08.2013) The requirements to the structure and activities of healthcare offices, the procedure for opening those, and the documentation which they shall keep, shall be set out in regulations issued by the Minister of Health in consultation with the Minister of Education and Science, Minister of Finance, the Minister of Labour and Social Policy and the chairman of the Minister of Youth and Sports.

(3) (Amended, SG No. 95/2007, SG No. 41/2009, effective 2.06.2009) The State Budget of the Republic of Bulgaria Act shall specify, on an annual basis, the financing by the central and local governments of the health activities for children and pupils, of the equipment and consumables for, and the performance of the activities for the respective year at the healthcare offices opened under this Act.

(4) (New, SG No. 95/2007, amended, SG No. 41/2009, effective 2.06.2009) The regulations under Paragraph (2) shall also specify the minimum number of children or pupils needed for the healthcare offices under Paragraph (1) to be opened, as well as the requirements for the equipment and consumables therein.

Article 26a

(New, SG No. 81/2006)

(1) Opticians' shops shall carry out activities related to:

1. (supplemented, SG No. 98/2010, effective 14.12.2010) health consultations on eyesight problems provided by a medical practitioner who has undergone recognised specialist training in ophthalmology or who has obtained professional qualification as per the relevant medical standard established under Article 6(1) of the Medical-Treatment Facilities Act;

2. undertaking measures for sight correction prescribed by a doctor;

3. manufacture and sale of optical glasses and ophthalmic optics materials.

(2) Opticians' shops shall be managed by persons who have acquired higher education with the educational qualification degree of "Master" in the occupational division of "Medicine" with acknowledged specialty in ophthalmic diseases, or by persons with the professional qualification in the occupations of "optical technician" or "optometrist (ophthalmic optician)" and with at least one year experience in this specialty.

(3) The manufacture and sale of optical glasses and ophthalmic optics materials shall be carried out by persons with professional qualification in the occupations of "optical technician" or "optometrist (ophthalmic optician)".

(4) (New, SG No. 98/2010, effective 14.12.2010) Health consultations under Paragraph 1(1) may be provided only in an opticians' shop that operates under a contract entered into with a medical practitioner who has undergone recognised specialist training in ophthalmology.

Article 26b

(New, SG No. 81/2006, amended, SG No. 98/2010, effective 1.01.2011)

(1) Opticians' shops under Article 26a(1) shall be opened as per the procedure laid down in Article 36.

(2) The requirements about the organisation and operations of opticians' shops shall be determined by an ordinance of the Minister of Health.

Section V
Health Information and Documentation

Article 27

(1) Health information shall include the personal data related to the health condition, the physical and mental development of individuals, as well as any other information contained in medical prescriptions, instructions, protocols, certificates and other medical records.
(2) (Amended, SG No. 98/2010, effective 1.01.2011) Medical treatment and healthcare facilities, RHIs, medical practitioners, dental practitioners, pharmacists and other medical specialists, as well as non-medical specialists with higher non-medical education who work within the national healthcare system, shall collect, process, use and store health information.
(3) The form and content and the terms and procedures for the processing, use and storage of medical records and for the exchange of medical statistical information shall be set out in regulations.

Article 28

(1) Health information may be disclosed to this parties in any of the following cases:
1. the treatment of the person continues at another medical facility;
2. there exists a threat to the health or life of other persons;
3. it is necessary for identifying a human corpse of for establishing the reasons for the death;
4. it is necessary for the needs of the state health control to prevent epidemics or the spread of infectious diseases;
5. it is necessary for the needs of medical expert activities and the social security scheme;
6. it is necessary for the needs of medical statistics or medical research, having deleted the data identifying the patient;
7. (amended, SG No. 98/2010, effective 1.01.2011) it is necessary for the needs of the Ministry of Health, the National Health Information Centre, NHIF, RHIs and the National Statistical Institute;
8. (new, SG No. 60/2012, effective 7.08.2012, supplemented, SG No. 102/2015, effective 1.01.2016) it is necessary for the needs of insurers, licensed under Section I of Annex 1 or item 2 or items 1 and 2 of Section II, letter "A" of Annex 1 of the Insurance Code.
(2) In the cases falling under Item 2 of Paragraph (1), the information shall be disclosed upon notification of the person concerned.
(3) The persons under Article 27 (2) shall ensure the protection of the health information they keep against unauthorised access.

Article 28a

(New, SG No. 41/2009, effective 2.06.2009, amended, SG No. 98/2010, effective 14.12.2010, SG No. 15/2013, effective 1.01.2014)
While performing their functions, the Minister of Health, the budget authorisers under the Ministry of Health, as well as medical treatment facilities to which a register of national importance has been created on the grounds of a statutory instrument shall be entitled to free-of-charge access to information registers established and maintained using budgetary funds.

Article 28b

(New, SG No. 41/2009, effective 2.06.2009)
(1) Patients shall be entitled to be provided by the respective medical treatment facilities with health information pertaining to their health status, including copies of their medical records.
(2) Patients shall be entitled to authorise in writing another person to review their medical records, as well as to make copies thereof.
(3) In case of the patient’s death, their heirs and lineal or collateral relatives up to four times removed from them inclusive shall be entitled to review the health information on the deceased, as well as to make copies of their medical records.

Article 28c

(New, SG No. 41/2009, effective 2.06.2009)

Medical specialists and staff of medical treatment facilities shall be prohibited from disclosing information on the patients, which became known to them while performing their official duties.

Section VI
(New, SG No. 102/2018, effective 1.01.2019)
National Health Information System

Article 28d

(New, SG No. 102/2018, effective 1.01.2019)

(1) A National Health Information System administered and kept by the Ministry of Health is created.

(2) The National Health Information System shall be created and kept on the basis of the following principles:

1. guaranteeing that the data submitted and stored is up-to-date and accurate;
2. ensuring an adequate data exchange environment;
3. guaranteeing regulated and controlled access to the data in the electronic information system, subject to the statutory requirements of the law;
4. ensuring operational compatibility and information security.

(3) Information on the health status of the population shall be collected, processed and stored in the National Health Information System by creating and maintaining an electronic health record for every citizen.

(4) (Supplemented, SG No. 21/2021, effective 12.03.2021) The information system referred to in Paragraph 1 shall include the electronic health records of citizens and all registers, information databases and systems which according to the ordinance under Paragraph 6 or other normative act are kept by the Ministry of Health and its second-level budget authorisers, by health and healthcare institutions, by the National Health Insurance Fund and by the insurance companies licensed in accordance with Item 2 or in accordance with Items 1 and 2 of Section II, letter A of Appendix 1 to the Insurance Code.

(5) For the needs of the information system referred to in Paragraph (1), data regarding the civil registration of individuals in accordance with the procedure established by the Civil Registration Act shall be provided free of charge by the Population Register – Population National Database kept by the Ministry of Regional Development and Public Works through Directorate General Civil Registration and Administrative Services.

(6) For the purpose of creating and maintaining the electronic health records of citizens, the medical treatment facilities and the healthcare facilities shall submit information to the Ministry of Health; the type of said information, the manner of its provision and the terms and procedure for its provision shall be determined by an ordinance of the Minister of Health.

(7) The ordinance referred to in Paragraph (6) shall also define the conditions and procedure for keeping the registers, information databases and systems that form part of the National Health Information System.

Article 28e

(New, SG No. 102/2018, effective 1.01.2019)

(1) The following shall have the right to free access to the National Health Information System:

1. each citizen: to the information in his/her electronic health record;
2. medical treatment facilities, healthcare facilities and the National Health Insurance Fund in the course of and in connection with performing their functions;
3. insurance companies licensed in accordance with Item 2 or in accordance with Items 1 and 2 of Section II, letter A of Appendix 1 to the Insurance Code;
4. state bodies for which access to registers of national importance is provided by law.

(2) Access to the information in the electronic health record of citizens and access for the persons referred to in Items 2, 3 and 4 of Paragraph (1) shall be provided only following an explicit written consent under conditions and according to a procedure determined by the ordinance referred to in Article 28d, Paragraph (6).

Chapter Two
HEALTH PROTECTION ACTIVITIES
Section I
General Provisions

Article 29

(1) (Previous text of Article 29, supplemented, SG No. 58/2019) Government and municipal bodies and institutions shall plan, develop and implement a policy aimed at protecting the citizens' health by ensuring a healthy environment, training for healthy life style and health prevention.
(2) (New, SG No. 58/2019) The activities of the municipalities to implement policies in the field of health prevention among the population and the medical practitioners during and in connection with the medical care provided can be supported by health mediators.
(3) (New, SG No. 58/2019) The Minister of Health shall define in an ordinance the requirements for the activity of health mediators.
(4) (New, SG No. 58/2019) The activity referred to in Paragraph (2) may also be assisted by non-profit legal entities with proven experience in the respective field under conditions and according to procedures and criteria laid down in the ordinance referred to in Paragraph (3).

Article 30

(1) Medical treatment facilities shall carry out preventive checks and dispensary registration for the purposes of protecting the citizens' health and capability for work.
(2) Persons of higher health risk or diseases shall be subject to dispensary registration.
(3) The terms and conditions and the financing of preventive checks and the dispensary registration, as well as the list of diseases for which dispensary registration is required shall be set out in regulations issued by the Minister of Health.

Section II
Ensuring a Healthy Environment

Article 31

(1) The central and local governments, legal entities and individuals shall carry out their activities by ensuring the protection of the environment against biological, chemical, physical and social factors which are harmful to the human health.
(2) In the course of their activities, legal entities and individuals shall observe the existing health requirements.

Article 32

(1) (Amended, SG No. 8/2011, effective 25.01.2011) The Minister of Health shall lead the national system for analysis, assessment and control of noise in urban areas and public buildings and of pollutants in drinking water.
(2) The Minister of Health shall analyse and assess the environment factors at the national level in the annual report under Article 5 (2) and propose measures to limit their harmful impact on the health of citizens.
(3) (New, SG No. 98/2010, effective 1.01.2011) The Minister of Health shall be in charge of the national system for analysis, assessment and control of non-ionising radiation within urbanised areas and public buildings.
(4) (Renumbered from Paragraph 3, amended, SG No. 98/2010, effective 1.01.2011) Regional health inspectorates shall monitor, analyse and assess the factors of the environment within the territory of the region and propose measures to limit their harmful impact on the health of citizens.
(5) (Renumbered from Paragraph 4, SG No. 98/2010, effective 1.01.2011) The government bodies performing analysis, assessment and control of the parameters of the environment shall provide the Ministry of Health with the data needed for the health risk assessment.

Article 33

(Amended, SG No. 41/2009, effective 2.06.2009)

(1) The Minister of Health shall organise epidemiological surveys to establish the links between environmental pollution and public health status.
(2) The Council of Ministers and/or municipal councils shall adopt and finance programmes to carry out activities related to the protection, improvement and restoration of the health of people living in settlements for which links between environmental pollution and public health status have been found.

Article 34

(1) (Repealed, SG No. 41/2009, effective 2.06.2009).
(2) The health requirements to public use facilities, products, goods and activities of importance to human health, as well as the maximum allowed levels of factors of the environment shall be set out in regulations issued by the Minister of Health, unless another law provides otherwise.
(3) (Amended, SG No. 24/2019, effective 1.07.2020 - amended, SG No. 101/2019) The health requirements to persons working at childcare facilities, social and integrated health and social services for residential care, water supply facilities, enterprises producing or trading in foods, barbers' shops, hairdressers' shops and beauty salons shall be set out in regulations issued by the Minister of Health.

Article 35

(Amended, SG No. 82/2012, effective 26.11.2012)
The state health control authorities shall take part in the membership of the expert boards for physical planning and development, coordinate development plans, if necessary, participate in the assessment of the compliance of investment projects, where the latter is subject to approval by an expert board of the approving administration or requested by individuals or legal entities, and give opinion on the preparedness of construction works to be set into operation under the Spatial Development Act.

Article 36

(1) (Amended, SG No. 34/2006, SG No. 98/2010, effective 1.01.2011, regarding sentence two - effective 1.07.2011, SG No. 85/2017) Any person opening a public use facility shall notify the respective RHI which has jurisdiction over the location of the facility no later than the commencement date of its operation. The notification shall contain the address of the facility, the types of activities performed therein, the name and permanent address of the person pursuing the activities and, in the case of a trader, the latter's Unified Identification Code. The notification may be submitted electronically, signed with an advanced electronic signature, advanced electronic signature based on a qualified certificate for electronic signatures, or qualified electronic signature pursuant to the requirements of 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 (OJ, L 257/73 of 28.8.2014), hereinafter referred to as "Regulation (EU) No. 910/2014", and of the Electronic Document and Electronic Trust Services Act and the Electronic Government Act.
(2) (Amended, SG No. 98/2010, effective 1.01.2011) Within one month of the notification, the state health control bodies shall conduct an inspection in respect of the compliance with health requirement in the facility.
(3) (Amended, SG No. 98/2010, effective 1.01.2011) Regional health inspectorates shall establish and maintain a public register of public use facilities under terms and conditions set out in regulations issued by the Minister of Health.
(4) (Supplemented, SG No. 81/2006, amended, SG No. 98/2010, effective 1.01.2011) Paragraph (1) shall not apply to medical treatment facilities; enterprises for production of and wholesale trade in medicines; pharmacies; drugstores; enterprises for production, storage and trade in foods; and public catering facilities.

Article 37

(1) (Amended, SG No. 41/2009, effective 2.06.2009) At the request of the parties concerned, the Chief State Health Inspector shall issue a health certificate for the export of products and goods of importance to human health, which have been manufactured in the country, to certify that these products and goods have been placed on the market in conformity with the requirements of national legislation and are being distributed freely on the territory of the country.

(2) (New, SG No. 1/2014, effective 3.01.2014) For the purposes of the issuance of a health certificate for the export of products and goods of importance to human health, the party concerned shall file an application to the Chief State Health Inspector, specifying:

1. the name, seat and principal office of business of the party concerned;
2. the name of the country to which the products or the goods are exported;
3. the justification of the need for the issuance of a health certificate;
4. for cosmetic products - details of the reference number under which the product has been notified in the Notification Portal for Cosmetic Products of the European Commission pursuant to Article 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), hereinafter referred to as "Regulation (EC) No. 1223/2009".

(3) (New, SG No. 1/2014, effective 3.01.2014) The following shall be attached to the application under paragraph 2:

1. details of the single identification code of sole proprietors and legal persons in the Companies Register and - for the companies registered in a Member State of the European Union or a state which is a party to the European Economic Area Agreement - a document on the current registration under the national laws issued by a competent authority of the respective state;
2. a list of the products and goods to be exported in the Bulgarian language with their precise name, trademark, type of packaging and name and address of the manufacturer and - for cosmetic products - also the category and type of the cosmetic product;
3. assessment of the safety of the cosmetic product when an application for the issuance of a cosmetic products export certificate is filed;
4. a document on the payment of the state fee.

(4) (New, SG No. 1/2014, effective 3.01.2014) Where the documents under paragraphs 2 and 3 are found to be incomplete or irregular, the applicant shall be advised thereof within seven working days and the time limits for the issuance of the health certificate shall be stayed;

(5) (New, SG No. 1/2014, effective 3.01.2014) The health certificate for the export of products and goods of importance to human health shall be issued within 15 working days as from the date of filing of the application under paragraph 2 or as from the date of removal of the incompleteness or irregularity under paragraph 4 respectively.

(6) (New, SG No. 1/2014, effective 3.01.2014, amended, SG No. 85/2017) The application under paragraph 2 may be filed also online, signed with an advanced electronic signature, advanced electronic signature based on a qualified certificate for electronic signatures, or qualified electronic signature pursuant to the requirements of Regulation (EU) No. 910/2014 and of the Electronic Document and Electronic Trust Services Act, and the Electronic Government Act.

(7) (New, SG No. 1/2014, effective 3.01.2014) The refusal to issue a health certificate shall be subject to appeal pursuant to the Code of Administrative Procedure.

(8) (Renumbered from Paragraph 2, SG No. 1/2014, effective 3.01.2014) The Minister of Health shall issue regulations to set out the terms and conditions for the issuance of health certificates for the export of products and goods of importance to human health.

(9) (New, SG No. 41/2009, effective 2.06.2009, renumbered from Paragraph 3, SG No. 1/2014, effective 3.01.2014) The health certificate provided for in Paragraph (1) shall be valid for a period of three years.

(10) (Renumbered from Paragraph 3, amended, SG No. 41/2009, effective 2.06.2009, renumbered from Paragraph 4, SG No. 1/2014, effective 3.01.2014) State Health Control Authorities shall issue opinions on the safety and/or conformity with legal requirements of products and goods of

importance to human health pursuant to the provisions of Council Regulation (EEC) No. 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.

Article 37a

(New, SG No. 1/2014, effective 3.01.2014)

(1) The Ministry of Health shall create and maintain a register of the health certificates issued for the export of products and goods of importance to human health. The register shall be public and shall contain:

1. the number and date of the export certificate;
2. the name of the exporting company;
3. the name of the manufacturer;
4. the state to which the product is exported;
5. the list of the products and goods specified in the export certificate.

(2) A separate section shall be set aside in the register under Paragraph 1, where the persons having submitted applications for issuance of health certificate for export shall be recorded in the order of submission and any documents appended to such applications shall be described. The processing of the files, compiled in regard to each application, shall be reflected in that section.

(3) The regulations under Article 37(8) shall specify the terms and procedures for the maintenance of the register under paragraph 1.

Article 38

(1) (Amended, SG No. 59/2006) Where health requirements are not observed in public use facilities, as regards products, goods or in the course of activities of importance to human health and of the maximum permissible levels of environmental factors, state health inspectors shall issue mandatory instructions and shall specify the deadline for the elimination of the violations.

(2) (Amended, SG No. 98/2010, effective 1.01.2011) In the event of failure to fulfil the mandatory instructions within the prescribed time limits, the RHI director or the NCRRP director respectively shall issue an order to stop the operation of the facility or parts thereof or to discontinue the respective activity pending the elimination of the violations.

(3) (Amended, SG No. 98/2010, effective 1.01.2011) Where an immediate threat exists to human life or health or for the spread of infectious diseases or for the occurrence of poisoning, state health inspectors shall stop the operation of the facility or parts thereof or to discontinue the respective activity immediately, specify the remedies and advise the RHI director forthwith.

(4) (Amended, SG No. 41/2009, effective 2.06.2009, SG No. 98/2010, effective 1.01.2011) Within 48 hours of the stop or discontinuation, the RHI director or the NCRRP director respectively shall issue an order to confirm or revoke the instruction to stop the operation of the facility or to discontinue the respective activity.

(5) Upon the fulfilment of the mandatory instructions and measures, the body which has issued the order shall allow the recovery of the activity or the operation of the facility by issuing an order.

Article 39

(1) Where any doubts exist as to the safety of products and goods of importance to human health, the State Health Inspector shall:

1. issue instructions in writing to stop the sales of the goods of importance to human health and deliver them to the party concerned or its representative with a signed receipt;
2. (amended, SG No. 98/2010, effective 1.01.2011) take samples for laboratory tests and for expert opinion and report in the presence of the party concerned or its representative and provide them to the RHI laboratory.

(2) The State Health Inspector shall advise the party concerned of the results of the laboratory tests and the expert opinion and report within three days of their reception.

(3) (Amended, SG No. 98/2010, effective 1.01.2011) Where the results of the laboratory tests and the expert opinion and report are contested, repeated tests shall be made at the request of the party

concerned given in writing to the Chief State Health Inspector through the RHI Director within three days of reception of the results from the initial tests.
(4) (Amended, SG No. 98/2010, effective 1.01.2011) In the cases under Paragraph (3), the repeated tests shall be conducted by another RHI designated by the Chief State Health Inspector.
(5) The results of the tests conducted under Paragraph (4) shall not be subject to contesting.

Article 40

Where the products and goods are obviously unfit for use and the party concerned submits no objections in writing to this conclusion to the state health inspector, no laboratory tests and expert opinions and reports shall be made.

Article 41

(1) Where the results of the laboratory tests and the expert opinion and report confirm the compliance of the products and goods with the health requirements, the state health inspector shall check them for any changes occurred during the stop and revoke in writing the instruction to stop the sale within three days of receipt of the results.
(2) Where the results of the laboratory tests and the expert opinion and report show that the products and goods do not comply with the health requirements, the state health inspector shall propose the issuance of an order to process or to use in a processed or unprocessed form for other purposes or to destroy the products and goods of importance to human health.

Article 42

(1) (Amended, SG No. 98/2010, effective 1.01.2011) The order to process or to use in a processed or unprocessed form for other purposes or to destroy the products and goods of importance to human health shall be issued by the RHI or NCRRP director for products and goods worth up to BGN 100,000 and by the Chief State Health Inspector for products and goods worth more than BGN 100,000.
(2) Within seven days of the effective date of the order under Paragraph (1), the products and goods shall be delivered for processing, use for other purposes or destruction always in the presence of a state health inspector for which a protocol shall be drawn up. The protocol shall be attached to the order under Paragraph (1).

Article 43

(1) The terms and conditions for taking samples and conducting the laboratory tests, analyses and expert opinions and reports needed for the purposes of the state health control shall be set out in regulations issued by the Minister of Health.
(2) (Amended, SG No. 98/2010, effective 1.01.2011) The costs of the laboratory tests for the needs of the state health control shall be borne by RHI.
(3) (New, SG No. 41/2009, effective 2.06.2009) In the case of repeated laboratory tests where results from laboratory analyses and expert examinations have been contested, the cost of laboratory tests shall be covered by the contesting party, if the results from the initial tests have been confirmed.

Article 44

Individuals and legal entities shall fulfil the mandatory instructions of state health inspectors and the order of the state health control authorities.

Article 45

(1) The enforceable administrative measures under this Section shall be subject to appeal pursuant to the Code of Administrative Procedure. The enforceable administrative measures shall be executed immediately.
(2) The enforceable administrative measures under this Section shall be subject to administrative appeal as follows:
1. (amended, SG No. 98/2010, effective 1.01.2011) those issued by a state health inspector – to the RHI director and the NCRRP director;

2. (amended, SG No. 98/2010, effective 1.01.2011) those issued by the RHI director and the NCRRP director – to the Chief State Health Inspector;
3. those issued by the Chief State Health Inspector – to the Minister of Health.

Article 46

(Amended, SG No. 98/2010, effective 1.01.2011)
State fees, in amounts set out in a tariff approved by the Council of Ministers, shall be paid for the issuance of documents and for other services provided under this Act by the state health control authorities and national centres for public health affairs.

Article 47

The facts and circumstances which become known to the officials exercising state health control in the discharge of their duties shall constitute an official secret, except for the cases of an existing threat to the health and life of citizens.

Article 48

(Amended, SG No. 98/2010, effective 14.12.2010)
The bodies of the Ministry of Interior, the other central and local government authorities and the heads of institutions, organisations, natural and legal persons shall provide the necessary support and assistance to state health inspectors in the exercise of their powers.

Section III
Health Requirements to Cosmetic Products

Article 49

(Amended and supplemented, SG No. 41/2009, effective 2.06.2009, amended, SG No. 82/2009, effective 16.10.2009, SG No. 1/2014, effective 3.01.2014)
(1) The cosmetic products placed on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use, taking into account their presentation, labelling, instructions for use and disposal, and any other indication provided by the manufacturer, the distributor and the importer.
(2) Cosmetic products placed on the market are safe, where:
1. good manufacturing practice is complied with pursuant to Article 8 of Regulation (EC) No. 1223/2009;
2. the products have undergone safety assessment pursuant to Article 10 of Regulation (EC) No. 1223/2009;
3. the requirements for the cosmetic product information file are complied with pursuant to Article 11 of Regulation (EC) No. 1223/2009; in the cases, in which the file is kept within the territory of the Republic of Bulgaria, the responsible person shall provide easy access of the competent authorities to the file in the Bulgarian language; the file shall be made readily accessible in electronic or other format at the address of the responsible person indicated on the label.
4. the provisions concerning the sampling and analysis are complied with pursuant to Article 12 of Regulation (EC) No. 1223/2009;
5. the requirements for notification prior to the placement of the cosmetic product on the market are complied with pursuant to Articles 13 and 16 of Regulation (EC) No. 1223/2009;
6. the restrictions for the substances used in cosmetic products are complied with pursuant to Articles 14, 15 and 17 of Regulation (EC) No. 1223/2009;
7. the requirements related to animal testing are complied with pursuant to Article 18 of Regulation (EC) No. 1223/2009;
8. the labelling requirements are complied with pursuant to Article 19, paragraphs 1, 2, 5 and 6 of Regulation (EC) No. 1223/2009; the information under Article 19(1)(b), (c), (d) and (e) and paragraphs 2, 3 and 4 shall be written also in the Bulgarian language;
9. the requirements for product claims are complied with pursuant to Article 20 of Regulation (EC) No. 1223/2009;

10. the requirements for access to information for the public are complied with pursuant to Article 21 of Regulation (EC) No. 1223/2009;
11. the requirements for communication of serious undesired affects are complied with under Article 23 of Regulation (EC) No. 1223/2009;
12. the requirements for the information on substances used in cosmetic products are complied with pursuant to Article 24 of Regulation (EC) No. 1223/2009.

Article 50

(Amended, SG No. 41/2009, effective 2.06.2009, SG No. 1/2014, effective 3.01.2014)
(1) The Minister of Health and the State Health Control authorities shall be designated competent authorities within the meaning of Article 34(1) of Regulation (EC) No. 1223/2009.
(2) The Clinic for Toxicology of the University Multi-profile Hospital for Active Treatment and Emergency Medical Aid "N.I. Pirogov" EAD shall be designated poison centre within the meaning of Article 13(6) of Regulation (EC) No. 1223/2009.
(3) The information provided by the European Commission pursuant to Article 13(1), (2) and (3) of Regulation (EC) No. 1223/2009 shall be used by the authority under paragraph 2 only for the purposes of medical treatment.
(4) The authority under paragraph 2 shall ensure the protection of the confidentiality of the information received pursuant to paragraph 2.

Article 51

(Amended, SG No. 98/2010, effective 14.12.2010, SG No. 1/2014, effective 3.01.2014)
(1) The Minister of Health shall periodically review and assess the functioning of the activities state health control authorities with regard to the surveillance of cosmetic products.
(2) The review and assessment under paragraph 1 shall be carried out at least every four years and the results thereof shall be communicated to the other Member States of the European Union and the European Commission and be made available to the public, by way of electronic communication and, where appropriate, by other means pursuant to Article 22 of Regulation (EC) No. 1223/2009.

Article 52

(Amended, SG No. 41/2009, effective 2.06.2009, SG No. 1/2014, effective 3.01.2014)
The Minister of Health shall issue regulations specifying:
1. the detailed rules for the presentation of the information under Article 19(1) of Regulation (EC) No. 1223/2009 on cosmetic products which have not been packaged in advance or are packaged at the time of their sale at the request of the consumer or have been packaged in advance for immediate sale;
2. the requirements for the efficiency of sunscreen products and the claims thereof;
3. the chemical methods for verification of the composition of cosmetic products.

Section IV
Activities to Impact Health Risk Factors

Article 53

(1) (Amended, SG No. 58/2019, amended and supplemented, SG No. 62/2022, effective 5.08.2022) The Minister of Health and other competent government authorities, together with non-governmental organisations, shall create conditions to restrict the use of tobacco and related products and the abuse of alcohol, to prevent the use of narcotic drugs as well as to prevent the use of nitrous oxide (heavenly gas) by persons under 18 years of age by:
1. carrying out promotional and preventive activities;
2. ensuring access to medical assistance and social protection of the persons affected.
(2) (Amended, SG No. 58/2019, amended and supplemented, SG No. 62/2022, effective 5.08.2022) The activities set out in Paragraph (1) shall be carried out through national programmes to restrict the use of tobacco and related products and the abuse of alcohol, to prevent the use of narcotic drugs as well as to prevent the use of nitrous oxide (heavenly gas) by persons under 18 years of age.

(3) (Effective 1.01.2006 - SG No. 70/2004, amended, SG No. 15/2013, effective 1.01.2014, SG No. 58/2019, amended and supplemented, SG No. 62/2022, effective 5.08.2022) One percent of the revenues to the state budget from excise taxes on tobacco products and spirits shall be used to finance national programmes to restrict the use of tobacco and related products and the abuse of alcohol, to prevent the use of narcotic drugs as well as to prevent the use of nitrous oxide (heavenly gas) by persons under 18 years of age.
(4) (Amended, SG No. 58/2019, amended and supplemented, SG No. 62/2022, effective 5.08.2022) Municipalities shall adopt and implement regional programmes to restrict the use of tobacco and related products and the abuse of alcohol, to prevent the use of narcotic drugs as well as to prevent the use of nitrous oxide (heavenly gas) by persons under 18 years of age.

Article 54

There shall be prohibited the sale of alcoholic beverages:
1. to persons below the age of 18;
2. to persons in a drunken state;
3. within the territory of kindergartens, schools, pupil boarding houses and medical treatment facilities;
4. at sports events;
5. at public events organised for children and pupils.

Article 54a

(New, SG No. 62/2022, effective 5.08.2022)
It is prohibited to sell nitrous oxide (heavenly gas) and refills with it, including online:
1. to persons below the age of 18;
2. within the territory of kindergartens, schools, pupil boarding houses and medical treatment facilities;
3. at sports events organised for children and pupils;
4. at public events organised for children and pupils;
5. (amended, SG No. 80/2023) in indoor public places, with the exception of sale for medical purposes and in the cases covered by Article 78a of the Food Act.

Article 55

(1) The direct advertising of spirits shall be prohibited.
(2) The indirect advertising of spirits and the advertising of wine and beer may not:
1. be targeted to persons below the age of 18 or broadcast in programmes or published in the press for them;
2. use persons below the age of 18 as participants;
3. relate the use of alcoholic beverages to sports and physical achievements or driving;
4. contain untrue assertions as to health benefits and social or sexual wellbeing or present abstinence or moderation in negative light.
(3) The indirect advertising of spirits may not be broadcast on the radio and television earlier than 10 o'clock p.m.

Article 56

(Amended, SG No. 41/2009, effective 1.06.2010, supplemented, SG No. 42/2010, effective 2.06.2010, amended, SG No. 40/2012, effective 1.06.2012)
(1) Smoking in indoor public places shall be prohibited.
(2) Smoking shall be also prohibited in premises with separate work places where work is done, as well as the premises ancillary and servicing thereto.
(3) As an exception, smoking shall be allowed in separate independent premises, situated in airport buildings.
(4) No persons below the age of 18 years shall be allowed in the separate independent premises referred to in paragraph 3.

(5) The separate independent premises referred to in paragraph 3 shall be separated with air-proof walls, tightly closed doors, shall be clearly designated and a ventilation installation shall be installed in them.
(6) The Council of Ministers shall specify in an ordinance the requirements to be met by the separate independent premises, referred to in paragraph 3.

Article 56a

(New, SG No. 42/2010, effective 2.06.2010, amended, SG No. 40/2012, effective 1.06.2012)
(1) (Previous text of Article 56a, SG No. 62/2022, effective 5.08.2022) Smoking shall be prohibited in the following open public places:
1. the sites and pavements adjacent to nursery schools, kindergartens, schools, pupils' dormitories and places where social services are provided to children;
2. the playgrounds;
3. places where events for children and pupils are organized;
4. sports facilities, summer cinemas and theatres - during sports and cultural events.
(2) (New, SG No. 62/2022, effective 5.08.2022) It is prohibited to use nitrous oxide (heavenly gas) in open public places specified in Paragraph (1), Items 1 - 3.
(3) (New, SG No. 62/2022, effective 5.08.2022, amended, SG No. 80/2023) It is prohibited to use nitrous oxide (heavenly gas) in indoor public places, with the exception of use for medical purposes and in the cases covered by Article 78a of the Food Act.

Article 56b

(New, SG No. 42/2010, effective 2.06.2010, repealed, SG No. 40/2012, effective 1.06.2012).

Article 56c

(New, SG No. 42/2010, effective 2.06.2010, repealed, SG No. 40/2012, effective 1.06.2012).

Section V
Infectious Diseases Monitoring
(Title amended, SG No. 98/2010, effective 1.01.2011)

Article 57

(1) Border health control shall be exercised, if needed, to protect the country against the spread of particularly dangerous infectious diseases.
(2) The terms and conditions for the border health control shall be set out in regulations issued by the Council of Ministers.

Article 58

(1) Mandatory immunization shall be performed to protect citizens against infectious diseases.
(2) The Minister of Health shall issue regulations to specify the persons subject to immunization, as well as the terms and conditions for the performance of:
1. mandatory planned immunization and re-immunization included in the immunization calendar of the Republic of Bulgaria;
2. special immunization and re-immunization performed at specific indications;
3. recommended immunization.
(3) The regulations under Paragraph (2) shall set out also the specific requirements to and the application of individual serums, immunoglobulins and other bioproducts for preventive purposes.

Article 59

(1) (Previous text of Article 59, SG No. 98/2010, effective 14.12.2010) Where an emergency epidemic situation occurs or a tangible decline is observed in the immunization coverage, the Minister of Health may issue instructions in:
1. mandatory immunization and re-immunization of certain groups of the population other than those included in the immunization calendar;
2. mandatory immunization and re-immunization with substances other than those included in the immunization calendar;

3. immunization and re-immunization in ways other than those included in the immunization calendar;
4. the organisation of immunization campaigns, the opening of temporary immunization offices, the establishment of teams for on-site immunization and other emergency measures.
(2) (New, SG No. 98/2010, effective 14.12.2010) Medical treatment and health care facilities, regardless of their ownership, shall implement the measures mandated by the Minister of Health under Paragraph 1.

Article 60

(1) Patients with infectious diseases, persons in contact with them and infection carriers shall be subject to registration, mandatory notification and reporting.
(2) The Minister of Health shall issue regulations to specify the diseases under Paragraph (1) and the terms and conditions for registration, notification and reporting.
(3) The Minister of Health shall also specify in the regulations under Paragraph (2) the terms and conditions for supervision, early warning and undertaking of measures in the event of bioterrorism or emergence of new unknown infectious diseases.
(4) (Amended, SG No. 98/2010, effective 14.12.2010) The prevention organisation and the control in respect of infections related to medical services shall be set out in regulations issued by the Minister of Health.
(5) (Amended, SG No. 59/2006) The Minister of Health shall issue ordinances to specify the terms and conditions for diagnostics, prevention and control of certain infectious diseases.
(6) The terms and conditions for testing, notification and reporting of infection with the virus of the acquired immune deficiency syndrome shall be set out in regulations issued by the Minister of Health.
(7) (New, SG No. 98/2010, effective 14.12.2010) The procedure concerning the disclosure, examination and registration of a food-related disease outburst and the sampling procedure when conducting epidemiological examinations shall be set out in regulations of the Minister of Health.

Article 61

(Supplemented, SG No. 41/2009, effective 2.06.2009, amended and supplemented, SG No. 98/2010, effective 14.12.2010, amended, SG No. 28/2020, effective 13.03.2020, SG No. 44/2020, effective 14.05.2020)
(1) (Amended, SG No. 105/2020, effective 11.12.2020, SG No. 96/2023, effective 17.11.2023) Persons who are patients or infection carriers of anthrax, brucellosis, smallpox, viral haemorrhagic fever, diphtheria, ebola, yellow fever, typhoid fever, malaria, poliomyelitis, severe acute respiratory syndrome, tuberculosis with bacilli spread, cholera and plague, shall be subject to mandatory isolation.
(2) (Amended, SG No. 105/2020, effective 11.12.2020) Any and all persons who have had contact with persons referred to in Paragraph 1 shall be subject to mandatory quarantine. To prevent the spread of infectious diseases referred to in Paragraph 1, persons arriving on the territory of Bulgaria from other countries may also be subject to mandatory quarantine.
(3) (Amended, SG No. 105/2020, effective 11.12.2020) On the recommendation of the Chief State Health Inspector, the Minister of Health shall issue an order requiring the mandatory isolation of patients and infection carriers of infectious diseases not referred to in Paragraph 1 along with mandatory quarantine of the persons who have had contact with these, on the basis of a conducted assessment of the epidemic risk in place of the spread of the infectious disease in question.
(4) (Amended, SG No. 105/2020, effective 11.12.2020) The mandatory isolation of a person referred to in Paragraphs 1 or 3 shall proceed following an instruction from the Director of the relevant Regional Health Inspectorate or a Deputy Director authorised by them.
(5) (Repealed, SG No. 105/2020, effective 11.12.2020).
(6) (Amended, SG No. 105/2020, effective 11.12.2020) The mandatory quarantine of a person referred to in Paragraphs 2 or 3 shall proceed following an instruction from the Director of the relevant Regional Health Inspectorate or a Deputy Director authorised by them.

(7) (Amended, SG No. 105/2020, effective 11.12.2020) On the recommendation of the Chief State Health Inspector, the Minister of Health shall issue an order setting out the periods for the mandatory isolation referred to in Paragraphs 1 or 3 and for the mandatory quarantine referred to in Paragraphs 2 or 3, which shall be in line with the epidemic risk relevant to the spread of the infectious disease in question referred to in Paragraphs 1 or 3.
(8) (Amended and supplemented, SG No. 105/2020, effective 11.12.2020) Contact persons referred to in Paragraph 2 or 3 herein may not refuse to submit to a test for the purpose of establishing the fact whether the said person is a carrier of an infectious disease referred to in Paragraph 1 or 3, which test is appointed by an instruction from the Director of the relevant Regional Health Inspectorate or a Deputy Director authorised by them.
(9) (Amended, SG No. 105/2020, effective 11.12.2020) The Minister of Health shall approve a standard form to be used for instructions referred to in Paragraphs 4, 6 and 8.
(10) (New, SG No. 105/2020, effective 11.12.2020) An announcement for the instruction referred to in Paragraph 4, 6 or 8 issued to a person referred to in Paragraph 1, 2 or 3 shall be sent following the procedure in Article 18a(1), (2), (3), Paragraph 4, item 1 and Paragraph 8 of the Administrative Procedure Code or in one of the following ways:
1. verbal notification via a phone call to a cell or fixed phone number specified by the person, which notification shall be documented in writing and certified by the signature of the official who performed it and the written certification shall be attached to the file;
2. sending an electronic or short text message to an e-mail address or a cell phone number specified by the person.
(11) (New, SG No. 105/2020, effective 11.12.2020) In the cases under Paragraph 10, items 1 and 2, the person referred to in Paragraph 1, 2 or 3 shall be notified that they may receive the instruction in person after the expiration of the isolation or quarantine period. During the isolation or quarantine period, the instruction may be received only through a person authorised by the person referred to in Paragraph 1, 2 or 3.
(12) (New, SG No. 105/2020, effective 11.12.2020) The instruction referred to in Paragraph 10, item 1 shall be considered served from the date of the verbal notification, and the one referred to in Paragraph 10, item 2 – when within 24 hours from its sending the person confirms the receipt of the message by sending back an electronic or short text message to the e-mail address or cell phone number specified by the relevant Regional Health Inspectorate.
(13) (New, SG No. 105/2020, effective 11.12.2020) When the person does not send a confirmation for the receipt of the message referred to in Paragraph 10, item 2 within the term referred to in Paragraph 12, the notification shall be made following the procedure set out in Article 18a (1), (2), (3), Paragraph 4, item 1 and Paragraph 8 of the Administrative Procedure Code or via verbal notification following the procedure in Paragraph 10, item 1.
(14) (Renumbered from Paragraph 10, amended, SG No. 105/2020, effective 11.12.2020) Any and all instructions referred to in Paragraphs 4, 6 and 8 shall be subject to anticipatory enforcement.
(15) (Renumbered from Paragraph 11, amended, SG No. 105/2020, effective 11.12.2020) The orders referred to in Paragraphs 3 and 7 and the instructions referred to in Paragraphs 4, 6 and 8 shall be subject to appeal before the competent administrative court according to the procedure established by the Code of Administrative Procedure.
(16) (Renumbered from Paragraph 12, SG No. 105/2020, effective 11.12.2020) The orders referred to in Paragraphs 3 and 7 shall constitute general administrative acts issued under Article 73 of the Code of Administrative Procedure, published on the website of the Ministry of Health and subject to anticipatory enforcement.
(17) (New, SG No. 105/2020, effective 11.12.2020) The terms and procedure for implementing the mandatory isolation of a person referred to in Paragraph 1 or 3, the mandatory quarantine of a person referred to in Paragraph 2 or 3 and for the assessment of the existing epidemic risk referred to in Paragraph 3 shall be laid down in the ordinance referred to in Article 60(5).
(18) (New, SG No. 105/2020, effective 11.12.2020, amended, SG No. 32/2022, effective 26.04.2022) The criteria for determination of the contact persons referred to in Paragraphs (2) and

(3) shall be also specified in the ordinance under Paragraph (17) in accordance with the specifics of spread of the respective infectious disease referred to in Paragraphs (1) or (3), including epidemic potential, infectivity, pathogen transmission route, etc.

Article 61a

(New, SG No. 105/2020, effective 11.12.2020) (1) In order to prevent the spread of the infectious diseases referred to in Article 61(1) or (3), the mandatory isolation of patients and infection carriers of an infectious disease referred to in Article 61(1) or (3) may be carried out at an in-patient medical treatment facility.

(2) The mandatory isolation of a person referred to in Paragraph 1 at an in-patient medical treatment facility shall be carried out following an instruction issued by the Director of the relevant Regional Health Inspectorate or a Deputy Director authorised by them upon proposal of the treating physician or of the physician who has referred the person referred to in Paragraph 1 for a hospital stay on the basis of performed assessment of the existing epidemic risk from the spread of the respective infectious disease referred to in Article 61(1) or (3).

(3) The Minister of Health shall approve a standard form to be used for instruction referred to in Paragraph 2.

(4) An announcement for the issued instruction referred to in Paragraph 2 shall be sent to a person referred to in Paragraph 1 following the procedure set out in Article 61(10).

(5) The instruction referred to in Paragraph 2 shall be subject to anticipatory enforcement.

(6) The instruction referred to in Paragraph 2 shall be subject to appeal before the relevant Administrative Court pursuant to the Administrative Procedure Code.

(7) The terms and procedure for implementing the mandatory isolation of a person referred to in Paragraph 1 at an in-patient medical treatment facility and for the assessment of the existing epidemic risk referred to in Paragraph 2 shall be laid down in the ordinance referred to in Article 61(17).

Article 62

(1) (Amended, SG No. 98/2010, effective 14.12.2010) Natural and legal persons engaged in providing disinfection, pest control of insects and rodents shall notify the Ministry of Health no later than the commencement date of their operations.

(2) (Supplemented, SG No. 99/2013, amended, SG No. 58/2017, effective 18.07.2017, SG No. 102/2022, effective 1.01.2023) The terms and conditions for the activities under Paragraph (1) shall be set out in regulations issued by the Minister of Health and Minister of Agriculture.

Article 63

(Amended and supplemented, SG No. 98/2010, effective 1.01.2011, amended, SG No. 15/2013, effective 1.01.2014, supplemented, SG No. 23/2020, effective 14.03.2020, amended, SG No. 44/2020, effective 14.05.2020)

In the event of an immediate threat to the life and health of the public owing to the epidemic spread of a disease referred to in Article 61(1), an emergency epidemic situation shall be declared to protect the life and health of said public

(2) The emergency epidemic situation referred to in Paragraph (1) shall be declared for a fixed period by a dedicated decision of the Council of Ministers and following a proposal by the Minister of Health on the basis of an assessment of the epidemic risk in place conducted by the Chief State Health Inspector.

(3) An immediate threat to the life and health of the public referred to in Paragraph (1) shall exist where the assessment referred to in Paragraph (2) finds that the infectious disease referred to in Article 61(1):

1. is caused by a pathogen characterised by a high epidemic potential (infectivity of the virus, high mortality rate, multiple transmission routes and asymptomatic carriers) and/or its source and its transmission mechanism and route are uncommon or unknown; or

2. constitutes a serious threat to public health even where the number of confirmed cases in humans is small; or

3. may obstruct or slow down the implementation of public health control measures (including due to a lack of treatment and/or vaccine and/or existence of multiple outbreaks among others); or
4. cannot be deterred due to low immunity rates in the public; or
5. is uncommon in a given region, for a given season, or population group; or
6. is characterised by a more severe course than expected, a high morbidity rate and/or mortality rate or unusual symptoms; or
7. puts vulnerable or risk groups (children, the elderly, refugees, persons suffering immune deficiency and/or chronic conditions and others) at further risk; or
8. is confirmed to have cases in medical professionals.

(3a) (New, SG No. 32/2022, effective 26.04.2022) In the event of declared emergency epidemic situation in accordance with Paragraph (1), as well as in the cases covered by Paragraph (10), the Minister of Health shall implement a National Plan for Preparedness and Action in the Event of an Epidemic or Pandemic adopted in accordance with the procedure laid down in Article 3(3), and if no such plan has been 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 of the declaring of an emergency epidemic situation in accordance with Paragraph (1).

(3b) (New, SG No. 32/2022, effective 26.04.2022) The national plan referred to in Paragraph (3a) must set out the actions and the types of measures for limiting the spreading of a contagious disease specified in Article 61(1), including specific indicators, criteria and time limits for the introduction of temporary anti-epidemic measures referred to in Paragraphs (4) and (10) and for lifting introduced temporary anti-epidemic measures referred to in Paragraphs (4) and (10), in accordance with the specifics of the spread of the respective contagious disease specified in Article 61(1).

(4) (Supplemented, SG No. 32/2022, effective 26.04.2022) Where an emergency epidemic situation referred to in Paragraph (1) is declared, the Minister of Health shall issue an order introducing temporary anti-epidemic measures on the territory of Bulgaria or of a specific region following a recommendation by the Chief State Health Inspector in accordance of the measures, determined in the national plan under Paragraph (3a).

(5) The measures referred to in Paragraph (4) may also include a ban on entry into the territory of the country of nationals of other countries, with the exception of citizens with permanent, long-term or continued residence in the territory of the Republic of Bulgaria, as well as their family members.

(6) The measures referred to in Paragraph 4 may also include temporary restriction of movement within the territory of the country, as well as suspension or restriction of the operation or the mode of operation of public use facilities and/or other facilities or services provided to citizens.

(7) Temporary anti-epidemic measures referred to in Paragraph (4) may also be introduced on the territory of a specific region, municipality or settlement by an order of the Head of the relevant Regional Health Inspectorate, where said order is agreed with the Chief State Health Inspector.

(8) Medical treatment and health care facilitates, regardless of their ownership, shall implement the measures introduced under paragraphs 4 and 7.

(9) Central and local government authorities shall ensure the necessary conditions for the implementation of measures referred to in Paragraphs (4) and (7), while the resources for their implementation shall be provided from the state budget or the municipal budgets respectively.

(10) (New, SG No. 32/2022, effective 26.04.2022) In order to overcome the consequences after the cancellation of a emergency epidemic situation declared in accordance with Paragraph (1) and/or to prevent subsequent epidemic spread of a contagious disease specified in Article 61(1), as well in order to control the epidemic risk, the Minister of Health at a proposal by the Chief State Health Inspector may introduce by an order temporary anti-epidemic measures for the territory of the country or for a specific region for a certain period of time in accordance with the measures and time limits laid down in the national plan referred to in Paragraph (3a).

(11) (New, SG No. 32/2022, effective 26.04.2022) The temporary anti-epidemic measures referred to in Paragraph (10) may also be introduced on the territory of a specific region, municipality or settlement for a fixed period of time by an order of the Head of the relevant Regional Health

Inspectorate, where said order is agreed with the Chief State Health Inspector, in accordance with the measures and time limits laid down in the national plan referred to in Paragraph (3a).
(12) (New, SG No. 32/2022, effective 26.04.2022) The temporary anti-epidemic measures referred to in Paragraphs (10) and (11) may not include:
1. prohibition on entering the territory of the country;
2. restricting the movement within the territory of the country;
3. suspension of operation of public use facilities and/or other facilities or services provided to citizens;
4. requiring a document for access to the facilities and services specified in Item 3.
(13) (Renumbered from Paragraph (10), amended, SG No. 32/2022, effective 26.04.2022) The orders referred to in Paragraphs (4), (7), (10) and (11) shall be subject to appeal before the relevant Administrative Court in pursuance of the Administrative Procedure Code.
(14) (Renumbered from Paragraph (11), amended, SG No. 32/2022, effective 26.04.2022) The orders referred to in Paragraphs (4), (7), (10) and (11) shall constitute general administrative acts issued under Article 73 of the Code of Administrative Procedure, published on the website of the Ministry of Health or of the relevant Regional Health Inspectorate respectively and subject to anticipatory enforcement.

Article 63a

(New, SG No. 44/2020, effective 14.05.2020)
(1) In the event of epidemic spread of an infectious disease referred to in Article 61(3), the Minister of Health may issue an order introducing anti-epidemic measures on the territory of Bulgaria or a specific region for a fixed period of time on a recommendation by the Chief State Health Inspector.
(2) The anti-epidemic measures referred to in Paragraph (1) may also be introduced on the territory of a specific region, municipality or settlement for a fixed period of time by an order of the Head of the relevant Regional Health Inspectorate, where said order is agreed with the Chief State Health Inspector.
(3) In the event of epidemic spread of an infectious disease referred to in Article 61(3), anti-epidemic measures banning entry on the territory of Bulgaria by foreign nationals and temporary restrictions on freedom of movement on the territory of Bulgaria shall not be introduced.
(4) The orders referred to in Paragraphs (1) and (2) shall be subject to appeal before the competent administrative court according to the procedure established by the Code of Administrative Procedure.
(5) The orders referred to in Paragraphs (1) and (2) shall constitute general administrative acts issued under Article 73 of the Code of Administrative Procedure, published on the website of the Ministry of Health or of the relevant Regional Health Inspectorate respectively and subject to anticipatory enforcement.

Article 63b

(New, SG No. 80/2015, effective 16.10.2015, previous Article 63a, SG No. 44/2020, effective 14.05.2020)
(1) In the event of a crisis, including a mass influx of asylum-seekers in the territory of the Republic of Bulgaria and in case of risk to public health, the Minister of Health may order measures and actions to protect public health, which are different than the measures and actions in this section.
(2) The measures and actions under Paragraph 1 shall be coordinated by the Chief State Health Inspector on a national level, executed by the regional health inspectorates in whose territory the accommodation places are being established, and are funded from the state budget.

Article 63c

(New, SG No. 44/2020, effective 14.05.2020, supplemented, SG No. 105/2020, effective 11.12.2020)
In the event of (a threat of) an epidemic spread of infectious diseases referred to in Article 61(1) or (3), central and local government authorities, individuals and legal entities shall provide all the necessary assistance to state health control authorities.

Article 63d

(New, SG No. 103/2020, effective 4.12.2020, amended, SG No. 32/2022, effective 26.04.2022)

Regional governors shall organise and coordinate the implementation and control of the anti-epidemic measures referred to in Article 63(4, 7, 10) and (11) and in Article 63a (1) and (2), and of the measures referred to in Article 63b (1) on the territory of the respective region, and 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 against the Impact of Ionizing Radiation

Article 64

(1) (Amended, SG No. 102/2017, effective 1.01.2018) The protection of persons against the impact of ionizing radiation shall be carried out, while observing the principles and requirements of radiation protection.

(2) The protection under Paragraph (1) shall include:

1. control of the factors of the working and living environment in order to identify and reduce the exposure of persons to sources of ionizing radiation;
2. (supplemented, SG No. 102/2017, effective 1.01.2018) medical treatment of persons working with sources of ionizing radiation, including assessment of their medical fitness to perform specific professional duties;
3. dosimetric control to establish the internal and external exposure of persons working with sources of ionizing radiation;
4. assessment of the exposure and the radiation risk of the population as a whole or groups thereof;
5. medical monitoring of persons exposed to sources of ionizing radiation in the course of medical tests or treatment;
6. medical assistance to the community, individual groups thereof or persons working with sources of ionizing radiation in the event of radiation accident.

(3) (New, SG No. 41/2009, effective 2.06.2009, supplemented, SG No. 102/2017, effective 1.01.2018, SG No. 86/2023, effective 13.10.2023) Medical monitoring of the persons who work with sources of ionising radiation, including assessment of their medical fitness to perform specific professional duties, shall be carried out by medical practitioners, NCRRP and the medical treatment facilities which meet the requirements laid down in the ordinance provided for in Item 4 of Article 65(1). The medical monitoring of persons admitted to work in nuclear plants shall be performed through hired competent physicians that had attained specialist qualifications in accordance with Annex No. 3 to the ordinance referred to in Item 4 of Article 65 (1) of the Health Act and medical specialists organised in a structural unit within the plant.

(4) (New, SG No. 102/2017, effective 1.01.2018) The medical fitness of persons to perform specific professional duties shall be determined by a conclusion issued by a medical practitioner under Paragraph 3 with specialty in "Radiobiology" or "Radiation Hygiene". The conclusion can be appealed within 14 days of its receipt before a Medical Fitness Commission at the NCRRP.

(5) (New, SG No. 102/2017, effective 1.01.2018) The commission under Paragraph 4 shall be appointed by the NCRRP Director and shall comprise at least three medical practitioners with specialty in "Radiobiology" or "Radiation Hygiene".

(6) (New, SG No. 102/2017, effective 1.01.2018) The commission under Paragraph 4 shall pronounce on appeals within 14 days of their receipt with a ruling which is final. The ruling shall determine the medical fitness of persons to perform specific professional duties in an ionizing radiation environment.

Article 65

(1) The Minister of Health shall issue regulations to specify:

1. the terms and conditions for medical assistance and health norms to protect persons in the event of radiation accident;

2. the terms and conditions for ensuring protection of persons in the case of medical radiation;
3. the terms and conditions for the performance of individual dosimetric control of persons working with sources of ionizing radiation;
4. the health norms and requirements to work in an ionizing radiation environment;
5. the requirements to the protection of persons exposed to recurrent radiation as a result of the production of, trade in or use of raw materials, objects and goods with increased radionuclide content;
6. (new, SG No. 41/2009, effective 2.06.2009) the principal requirements for provision of radiation protection during work with sources of ionising radiation for medical purposes.
(2) (Repealed, SG No. 102/2017, effective 1.01.2018).

Article 65a

(New, SG No. 102/2017, effective 1.01.2018)
(1) The activities for testing the quality of the medical radiological equipment shall be performed by a legal entity or a sole trader, registered in the register under Article 65c, Paragraph (1).
(2) The legal entity or the sole trader shall appoint with a contract persons with a specialty in "Medical Radiology Physics" having at least 5 years of professional experience in the field of radiation therapy, nuclear medicine or imaging to perform the testing activities. Appointment of a person under a contract is not required where the sole trader has the necessary qualifications and experience and performs the test activities himself.
(3) To be registered in the register under Article 65c, the persons under Paragraph (1) shall submit to the Minister of Health an application enclosing therewith:
1. unified identification code or BULSTAT code, or a relevant document pursuant to the legislation of another Member State of the European Union or pursuant to the legislation of another state which is a party to the European Economic Area Agreement;
2. current certificate of registration for work with sources of ionizing radiation pursuant to Article 56, Paragraph (3) of the Safe Use of Nuclear Energy Act;
3. a list of the activities to be performed;
4. a list and identification data of the measuring devices and current certificates of calibration or checks, certifying the metrological characteristics of the measuring device;
5. the names of the person who will perform activities for testing the quality of the medical radiological equipment, and documents attesting to his/her qualification and experience.
(4) The application under Paragraph 3 can also be submitted by electronic means subject to the conditions and according to the procedure established by the Electronic Document and Electronic Trust Services Act and the Electronic Government Act.
(5) Within one month of receiving an application under Paragraph (3), the Minister of Health or an official authorised thereby shall rule by:
1. registering the person in the register under Article 65c and issuing a certificate of registration;
2. giving a motivated refusal of registration in the register under Article 65c and informing the applicant of this refusal.
(6) Where an irregularity is found, or when additional information is required, the Minister of Health or the official authorised thereby shall notify the applicant in writing and shall set a time limit for the removal of the irregularity and/or the provision of the additional information, which may not be shorter than 10 days. Until the removal of the irregularity and/or the provision of the additional information, the time limit under Paragraph (5) shall stop running.
(7) The certificate of registration shall contain data regarding the registered person, the person who will perform activities under Paragraph (1), a list of the activities covered by the registration, the name of the register and the registration number.

Article 65b

(New, SG No. 102/2017, effective 1.01.2018)
The Minister of Health or the official authorised thereby shall refuse registration in the register under Article 65c where:

1. false information or documents with false content have been submitted;
2. the person who will perform activities for testing the quality of the medical radiological equipment does not satisfy the requirements of Article 65a, Paragraph (2);
3. data or documents which do not satisfy the requirements of Article 65a, Paragraph (3), Items 2 and 4 have been submitted.

Article 65c

(New, SG No. 102/2017, effective 1.01.2018)
(1) A register of the persons who/which have obtained a certificate of registration for performing activities for testing the quality of medical radiological equipment shall be created and kept in the Ministry of Health.
(2) The register shall be public and the following shall be entered therein:
1. number and date of issue of the registration certificate;
2. name, seat and management address of the legal entity or the sole trader, unified identification code or BULSTAT code, or a relevant document pursuant to the legislation of another Member State of the European Union or pursuant to the legislation of another state which is a party to the European Economic Area Agreement;
3. data under Article 65a, Paragraph (3), Items 3 and 5.
(3) In a separate section in the register information regarding the persons who/which have submitted applications for issuing a certificate of registration, the number and type of the documents enclosed shall be entered, and the movement of the dossier shall be recorded. Entries shall be made in the order of receipt of applications.
(4) The Minister of Health shall deregister a person, who/which has obtained a certificate of registration for performing activities for testing the quality of medical radiological equipment, in the following cases:
1. upon a request by the person, wherewith the original of the issued certificate shall be enclosed;
2. upon termination of the legal entity or deregistration of the sole trader;
3. in the case of provision of false information or documents with false content which have served as grounds for registration of the person in the register;
4. in the case of cancelling or withdrawal of the certificate of registration for activities pursuant to Article 56, Paragraph 3 of the Safe Use of Nuclear Energy Act;
5. in the case of performing activities in violation of the requirements of Article 65a, Paragraph (2);
6. in the case of performing activities without holding current certificates of calibration or checks, certifying the metrological characteristics of the measuring device.
(5) A person registered in the register shall be obliged to notify the Ministry of Health in the event of change in the circumstances under Paragraph (2) within 7 days of the occurrence or becoming aware of the change, and in the circumstances subject to registration in the Commercial Register – within 7 days of their registration.

Article 65d

(New, SG No. 102/2017, effective 1.01.2018, supplemented, SG No. 77/2018, effective 1.01.2019)
The instruments under Article 65b and Article 65c, Paragraph (4) shall be subject to appeal before the relevant Administrative Court in accordance with the procedure established by the Administrative Procedure Code.

Article 66

(1) Medical ionizing radiation shall be allowed in any of the following cases:
1. diagnostics or treatment of patients;
2. health screening;
3. implementation of medical research programmes with the participation of volunteers.
(2) Medical ionizing radiation shall be allowed with regard to persons who consciously and voluntarily help other persons in the course of medical radiation without having any professional duty to do so.

(3) The medical radiation under Paragraph (1) shall be prescribed and conducted by medical doctors or doctors of dental medicine.
(4) The exposure of children to ionizing radiation within the framework of a health screening programme and the radiation involving high doses for the patient shall be conducted only by specialists who have undergone further specialised training.
(5) In the cases under Paragraph (1), the persons to whom medical radiation is applied shall be entitled to refuse diagnostics and treatment related to ionizing radiation at any point of time.

Article 67

(Amended, SG No. 102/2017, effective 1.01.2018) (1) Imaging studies for non-medical purposes using sources of ionizing radiation shall be allowed, subject to the principle of justifiability of radiation.
(2) The cases in which imaging studies under Paragraph (1) are allowed and the terms and conditions for their conducting shall be set out in an ordinance issued by the Minister of Health, the Minister of Finance and the Minister of Justice.

Article 68

(1) No medical ionizing radiation shall be applied to pregnant women, unless there exists a serious threat to their life or health. In the case of medical ionizing radiation of a woman in fertile age, medical specialists shall ask her whether she is pregnant or not.
(2) Where emergency aid is provided and the possibility for pregnancy cannot be ruled out, measures shall be taken to protect the health of the pregnant woman and the foetus.
(3) Medical radiation of a breast-feeding woman for diagnostics and/or treatment with the methods of nuclear medicine shall be allowed only in case there exists a serious threat to her life or health.

Article 69

(1) Where the patient is at home after treatment or diagnostics with radioactive substances, the medical specialist in charge of the treatment of diagnostics shall provide the patient with instructions in writing on how to limit the exposure of the family members or the persons taking care of the patient directly.
(2) The instructions under paragraph 1 shall be provided to the parent or the custodian of a patient who is a child or has been put under full legal incapacity or to the parent or guardian of a patient who is a young person or has been put under partial legal incapacity.

Article 70

(1) The state health control authorities may allow, by way of exception, the performance of activities by volunteers at higher levels of exposure in order to save human life or prevent greater exposure in the event of a radiation accident. The effective dose per person shall not exceed 50 milliSivert in any year or a total of 200 milliSivert for ten years.
(2) The persons under Paragraph (1) shall be subject to immediate medical testing and monitoring.

Article 71

(1) The Ministry of Health shall establish and maintain a register of the persons working or having worked in an environment of ionizing radiation.
(2) The terms and conditions for the registration, processing and storage of the data under Paragraph (1) shall be set out in regulations issued by the Minister of Health

Article 72

(1) Individuals and legal entities performing activities with sources of ionizing radiation shall:
1. allow staff from external organisations to work upon the presentation of a medical conclusion on the fitness of the employee to work in an ionizing radiation environment;
2. perform radiation monitoring and provide medical supervision of these persons during their work on the site;
3. submit the results of the radiation monitoring to the employer of the external organisation.

(2) The persons under Paragraph (1) shall notify the Ministry of Health of any deviations in the course of normal operation of the facilities, which may lead to exposure of citizens.
(3) The government authorities which perform monitoring of the radiation parameters of the environment shall provide the Minister of Health, from time to time, with data needed for health risk assessment purposes.
(4) (New, SG No. 98/2010, effective 1.07.2011, amended, SG No. 85/2017) The results under Paragraph (1), item 3 and the notifications under Paragraph 2 may be submitted electronically, signed with an advanced electronic signature, advanced electronic signature based on a qualified certificate for electronic signatures, or qualified electronic signature pursuant to the requirements of Regulation (EU) No. 910/2014, the Electronic Document and Electronic Trust Services Act and the Electronic Government Act.

Section VII
Protection of the Health of Citizens in the Performance of Works with Asbestos and Asbestos-containing Materials

Article 73
(1) (Amended, SG No. 59/2006, effective 21.07.2006, SG No. 98/2010, effective 1.01.2011) The works related to the demolition or removal of asbestos and/or asbestos-containing materials of buildings, structures, enterprises, installations or vessels shall be carried out upon reception of permission from the director of the RHI that has jurisdiction over the territory within which they are carried out.
(2) (Amended, SG No. 59/2006, effective 21.07.2006, SG No. 98/2010, effective 1.01.2011) In order to obtain a permission, the party concerned shall submit an application to the RHI:
1. application for issuance of permit;
2. a work plan, featuring concrete measures for providing the health and safety of workers and employees at work;
3. a list of workers and employees engaged;
4. attestation of training of workers and employees.
(3) (Amended, SG No. 59/2006, effective 21.07.2006) The work plan shall specify:
1. the type and expected duration of activities;
2. the location of activities;
3. the methods applied at activities involving asbestos or asbestos-containing materials;
4. the personal protection kits provided where necessary;
5. the characteristics of the equipment used for protection of:
(a) the workers and employees and for eradication of pollution with asbestos;
(b) other persons on location of or in proximity to the work done;
6. the planned activities for protection of the environment;
7. the procedure and means of proving the lack of risk from exposure to asbestos at work after completion of the works on demolition or removal of asbestos or asbestos-containing materials.
(4) (Amended, SG No. 59/2006, effective 21.07.2006) The work plan shall be developed in abidance by the requirement for removal of asbestos and/or asbestos-containing materials prior to the application of techniques for demolition, with the exception of the cases where works on said removal cause a greater risk for workers and employees than non-removal of the asbestos or asbestos-containing materials.
(5) (New, SG No. 59/2006, effective 21.07.2006) The training of workers and employees shall be conducted under conditions and by a procedure established by the ordinance referred to in Item 2 of Article 36 of the Health and Safety at Work Act.
(6) (Renumbered from Paragraph (5), SG No. 59/2006, effective 21.07.2006) No permission shall be required for emergency and rescue operations.

Article 74
(1) (Amended, SG No. 59/2006, effective 21.07.2006, SG No. 98/2010, effective 1.01.2011) Within three days of the application submission date, the RHI director shall forward ex officio, the

documents under Article 73(2) to the Regional Inspectorate for the Environment and Water that has jurisdiction over the location of the site for demolishing or removal of asbestos or asbestos-containing materials.
(2) (Amended, SG No. 98/2010, effective 1.01.2011) The Regional Inspectorate for the Environment and Water shall issue its opinion within 14 days of the date of receipt of the documents. Where no opinion is received by the RHI within the prescribed time limits, the Regional Inspectorate for the Environment and Water shall be presumed to have given its approval concerning the documents without any reservations.
(3) (Amended, SG No. 98/2010, effective 1.01.2011) The RHI director shall notify the applicant with regard to the recommendations of RHI and/or the Regional Inspectorate for the Environment and Water to change the work plan. In accordance with the recommendations and within one month of the notification, the applicant shall submit the work plan adjusted in conformity with the recommendations.
(4) (Amended, SG No. 59/2006, effective 21.07.2006, SG No. 98/2010, effective 1.01.2011) The permission for demolishing or dissembling of asbestos and/or asbestos-containing materials shall be issued by the RHI director within five days of the date of receipt of a positive opinion of the Regional Inspectorate for the Environment and Water or the adjusted work plan.
(5) (Amended, SG No. 98/2010, effective 1.01.2011) In the event of failure to implement the recommendations, the RHI director shall issue a reasoned permission refusal.

Section VIII
Resort Resources and Resorts

Article 75
(Amended, SG No. 98/2018, effective 27.11.2018) (1) Resort resources are mineral waters, curative peloids (curative mud), the beach strip and sea water and the areas with favourable bio-climatic conditions for preventive medicine, treatment and rehabilitation.
(2) Curative peloids (curative mud) are slime from firths and lagoons, slime from water sources, sedimentary mud from lakes, peat and bentonite clay.
(3) To allow the use of mineral waters for drinking, hygiene, curative, preventive, rehabilitation and sports-and-recreation purposes, the Minister of Health or an official authorised by him/her shall issue a hydrotherapeutic assessment under terms and according to a procedure established by the ordinance referred to in Article 77, item 1. The hydrotherapeutic assessment shall attest to the composition and properties of the mineral water from a specific water withdrawal facility at a mineral water deposit, and shall certify the purpose(s) and method(s) of the water's application.
(4) The hydrotherapeutic assessment under paragraph 3 shall be issued at the proposal of the director of the respective Basin Directorate or the municipality mayor managing/taking care of the mineral water from the respective mineral water deposit. A summary of the specific hydrogeologic conditions and exploitation characteristics of the water withdrawal facility shall be enclosed with the proposal.
(5) The hydrotherapeutic assessment under paragraph 3 shall be drawn up on the basis of analyses and conclusions from evaluations of the following:
1. the hydrogeologic conditions and exploitation characteristics of the mineral water deposit;
2. the mineral water's physical, physico-chemical, chemical, radiological and microbiological characteristics;
3. the mineral water's pharmacological, physiological and clinical effects.
(6) The hydrotherapeutic assessment under paragraph 3 shall be valid for a period of 10 years as of the date of its issue.
(7) The renewal of any hydrotherapeutic assessment shall be made as laid down in paragraphs 4, 5 and 6; the proposal for renewal must be submitted no later than 6 months before the expiration of the period under paragraph 6.
(8) The issued hydrotherapeutic assessments shall be published on the webpage of the Ministry of Health.

Article 76

(Amended, SG No. 98/2018, effective 27.11.2018) (1) Territories with categorized resort resources and opportunities for construction and operation of sites and facilities for preventive medicine, treatment, rehabilitation, recreation and tourism of the population shall be declared resorts.

(2) The declaration of the resorts shall be effected at the proposal of the Minister of Health by decision of the Council of Ministers which will be promulgated in the State Gazette.

Article 77

(Amended, SG No. 94/2005, SG No. 82/2009, effective 16.10.2009, SG No. 66/2013, effective 26.07.2013, SG No. 98/2014, effective 28.11.2014, SG No. 9/2015, effective 3.02.2015) The Minister of Health, jointly with the Minister of Regional Development and Public Works, the Minister of the Environment and Water and the Minister of Tourism, shall issue regulations specifying the conditions and procedure for:

1. (amended, SG No. 98/2018, effective 27.11.2018) the declaration, use of and protection of resort resources, resort zones and territories and the resorts themselves and the classification of the resorts;
2. (repealed, SG No. 98/2018, effective 27.11.2018);
3. the approval of the operational stock and use of curative mud deposits;
4. (repealed, SG No. 98/2018, effective 27.11.2018).

Article 78

(1) (Supplemented, SG No. 98/2018, effective 27.11.2018) Medical treatment facilities shall have priority use of mineral waters and curative mud for their medical activities, including the cases in which these resort resources are subject to the provisions of the Concessions Act.

(2) (Repealed, SG No. 41/2009, effective 2.06.2009).

Article 78a

(New, SG No. 40/2012)

(1) To protect life and human health and for the purposes of preventing water accidents, water areas and swimming pools for public use shall be secured and life-guard activities shall be organized.

(2) The requirements to the life-guard activities and the securing of water areas and swimming pools for public use shall be specified in an ordinance of the Council of Ministers.

Chapter Three
MEDICAL SERVICES
Section I
Accessibility and Quality of Medical Aid

Article 79

(1) (Previous text of Article 79, SG No. 102/2018, effective 1.01.2019) Medical aid in the Republic of Bulgaria shall be provided by applying methods and technologies approved by medical science and practice.

(2) (New, SG No. 102/2018, effective 1.01.2019) The requirement for the provision of medical aid laid down in Paragraph (1) shall also apply to the medical activities performed with respect to Bulgarian citizens abroad as specified in Article 82, Paragraph 1a.

Article 80

The quality of medical aid shall be based on medical standards approved pursuant to Article 6 (1) of the Medical Treatment Facilities Act and the Rules of Good Medical Practice adopted and approved pursuant to Item 4 of Article 5, of the Doctors' and Dentists Professional Organisations Act.

Article 81

(1) Each Bulgarian citizen shall be entitled to accessible medical aid under the terms and conditions of this Act and the Health Insurance Act.

(2) The right to accessible medical aid shall be exercised, while applying the following principles:

1. timeliness, sufficiency and quality of medical aid;

2. equality in the provision of medical aid with priority given to children, pregnant women and mothers of children aged below one year;
3. cooperation, consistency and coordination of the activities of medical treatment facilities;
4. respect for the patient's rights.
(3) The terms and conditions for the exercise of the right of access to medical aid under Paragraph (1) shall be set out in regulations issued by the Council of Ministers.

Article 82

(1) Beyond the scope of the mandatory health insurance of Bulgarian citizens, medical services shall be provided in relation to:
1. medical aid in emergency cases;
1a. (new, SG No. 102/2018, effective 1.01.2019) intensive care of individuals with no health insurance;
2. (new, SG No. 59/2006, supplemented, SG No. 41/2009, effective 1.07.2009) preventive examinations and tests and obstetric care for all women without health insurance, regardless of the manner of birth, within the scope and by a procedure determined by an ordinance of the Minister of Health;
3. (renumbered from item 2, SG No. 59/2006) inpatient psychiatric care;
3a. (new, SG No. 102/2018, effective 1.01.2019) complex dispensary (outpatient) follow-up of individuals with no health insurance who have a psychiatric condition;
3b. (new, SG No. 102/2018, effective 1.01.2019) treatment with methadone substitution and support psycho-rehabilitation and daily psycho-rehabilitation programmes;
4. (renumbered from Item 3, SG No. 59/2006) the provision of blood and blood products;
5. (renumbered from Item 4, SG No. 59/2006) transplantation of organs, tissues and cells;
6. (renumbered from Item 5, SG No. 59/2006) the mandatory treatment and/or mandatory isolation;
6a. (new, SG No. 102/2018, effective 1.01.2019) provision of medical activities for patients with infectious diseases according to a list established by an ordinance of the Minister of Health, including for preventing epidemiological risk;
6b. (new, SG No. 102/2018, effective 1.01.2019) complex dispensary (outpatient) follow-up of individuals with no health insurance who have skin and venereal diseases;
6c. (new, SG No. 102/2018, effective 1.01.2019) provision of medical activities for patients with nonspecific pulmonary diseases according to a list established by an ordinance of the Minister of Health;
7. (renumbered from Item 6, SG No. 59/2006, amended, SG No. 41/2009, effective 1.07.2009) expert examinations on the type and degree of disability and long-term incapacity for work;
8. (renumbered from Item 7, SG No. 59/2006, amended, SG No. 102/2018, effective 1.01.2019) the payment for the treatment of diseases under terms and conditions set out by the Minister of Health;
9. (renumbered from Item 8, SG No. 59/2006, amended, SG No. 102/2018, effective 1.01.2019) ensuring the sustainability of medical activities and specialised care provided to certain individuals in the course of the implementation of projects and programmes funded by the European structural and investment funds or by other international financial institutions and donors according to a list established by an ordinance of the Minister of Health;
10. (new, SG No. 106/2013, effective 1.01.2014) assisted reproduction.
(1a) (New, SG No. 102/2018, effective 1.01.2019) Beyond medical services referred to in Paragraph (1), Bulgarian citizens are entitled to a payment for medical and other services related to their medical treatment in Bulgaria or abroad depending on their disease, for which no other mechanisms are envisaged for financing with funds from the executive budget, the municipal budgets and from the budget of the National Health Insurance Fund or for which no insurance can be obtained in Bulgaria, subject to prior approval.
(2) Each Bulgarian citizen shall use:
1. (amended, SG No. 101/2012, effective 1.01.2013, SG No. 106/2013, effective 1.01.2014) vaccines for mandatory immunisation and re-immunisation, vaccines for specific indications and in

emergency situations, specific serums, immunoglobulins and other bioproducts related to the prevention of infectious diseases, as well as the technical means for their application;
2. the full range of anti-epidemic activities;
3. access to healthcare activities within the framework of national, regional and municipal health programmes.
(3) (Amended, SG No. 102/2018, effective 1.01.2019, supplemented, SG No. 99/2019, effective 17.12.2019) In the cases referred to in Paragraph (1a), individuals aged below 18 years shall be entitled to medical aid outside the scope of the mandatory health insurance; such medical aid shall also include payments from the executive budget for medical devices, highly specialised devices/appliances for individual use, dietary foods for special medical purposes, medicinal products not included in the list referred to in Article 262, Paragraph (1) of the Medicinal Products in Human Medicine Act. The treatment of oncological and onco-haematological diseases that began before the age of 18 years shall continue to be paid beyond that age until the end of treatment.
(4) Children accommodated at medical treatment facilities under Article 5 (1) of the Medical-Treatment Facilities Act shall be entitled to medical and social care free of charge.
(5) (Amended, SG No. 15/2013, effective 1.01.2014, supplemented, SG No. 102/2018, effective 1.01.2019) The activities under Paragraphs (1), (1a), (2), (3) and (4) shall be financed from the state budget and municipal budgets and used under terms and conditions set out in regulations issued by the Minister of Health.
(6) (New, SG No. 102/2018, effective 1.01.2019, supplemented, SG No. 18/2022, effective 4.03.2022) The scope of the medical and other services referred to in Paragraphs (1a) and (3), including whether they are provided in Bulgaria or abroad, and the use of medicinal products, dietary foods for special medical purposes, medical devices and highly specialised devices/appliances for individual use, the diseases of the persons for which such products, foods and devices are paid and the conditions and procedure in accordance with which they are approved and paid shall be determined by an ordinance of the Minister of Health. The time limit for the issuance of individual administrative acts for approval or refusal of the payments for the given medical and other services shall be up to one month.
(7) (New, SG No. 102/2018, effective 1.01.2019) Payments for medical and other activities referred to in Paragraphs (1a) and (3) in countries outside the European Union, the European Economic Area and the Swiss Confederation shall be allowed by way of exception where it is necessary to apply a method or a technology which is not applied in a country in the European Union, the European Economic Area and the Swiss Confederation and said method or technology is established in the medical science and practice in said country and its application with respect to patients results in benefits to patients.
(8) (New, SG No. 102/2018, effective 1.01.2019) Medical and other activities covered within the scope of the medical care referred to in Items 1 to 14 of Article 45 (1) of the Health Insurance Act shall not be paid for using funds from the state budget, regardless of whether an application has been made for such activities to be carried out in a country outside the European Union, the European Economic Area and the Swiss Confederation.

Article 82a

(New, SG No. 98/2010, effective 1.01.2011)
Municipalities may use self-generated revenues to support disease prevention and treatment of low-income or unemployed people, as well as other persons who have their permanent residence address registered with the respective municipality.

Article 82b

(New, SG No. 54/2012)
(1) The medical treatment facilities for in-patient health care shall be obliged to ensure for the patients any medical devices, required for their treatment.
(2) The medical devices under Paragraph (1) shall be ensured via the hospital pharmacies of the medical treatment facilities for in-patient health care.

(3) (Amended, SG No. 15/2013, effective 1.01.2014) Where the medical devices under Paragraph (1) would not be paid for by the National Health Insurance Fund or by the state budget, patients shall pay for them at the prices, at which the medical treatment facility would have purchased them.

Article 83

(Amended and supplemented, SG No. 18/2006, amended, SG No. 95/2006)

(1) (Supplemented, SG No. 9/2011, amended and supplemented, SG No. 32/2022, effective 26.04.2022) Foreigners who hold permits for long-term or permanent residence in the Republic of Bulgaria, foreigners with granted refugee status, humanitarian status and right to asylum, enjoy medical care under Articles 81 and 82 under the conditions and according to the procedure applicable to Bulgarian nationals.

(1a) (New, SG No. 32/2022, effective 26.04.2022) Foreigners to whom provisional protection has been granted are entitled to medical care and medical services under Articles 81 and 82 under the conditions and according to the procedures applicable to Bulgarian nationals, except where said medical care has been delivered in compliance with the rules for coordination of the social security systems within the meaning of § 1, item 22 of the supplementary provisions of the Health Insurance Act.

(2) (Supplemented, SG No. 32/2022, effective 26.04.2022) The procedures for access to medical aid of the persons under Paragraphs (1) and (1a) shall be set out by the ordinance under Article 81(3).

(3) (Amended, SG No. 32/2022, effective 26.04.2022) Foreign graduate students and PhD students, admitted for education in establishments of higher education and research in this country under the procedure of Decree of the Council of Ministers No. 103/1993 regarding carrying out of education activities among Bulgarians abroad (promulgated, SG No. 48/1993; corrected, SG No. 52/1993, amended, SG No. 54/1995, No. 20/1996, Nos. 38 and 73/1999, No. 101/2002, No. 89/2004) and Decree of the Council of Ministers, No. 228/1997 on admission of citizens of the Republic of Macedonia as graduate students in public higher educational establishments in the Republic of Bulgaria (promulgated, SG No. 42/1997, amended, No. 72/1999 and No. 101/2002), shall enjoy access to medical assistance under Article 81 and 82 under the terms and according to the procedure for Bulgarian citizens.

(4) Foreigners residing in the Republic of Bulgaria on a long or short-term basis or passing transit shall pay the value of the medical aid rendered to them at the prices set out by the medical establishment under the terms and conditions set out by the regulations of the Minister of Health, the Minister of Foreign Affairs and the Minister of Justice.

(5) Foreigners residing in the Republic of Bulgaria on a short-term basis or passing transit shall have health insurance or policy covering the costs of treatment and hospitalization during their stay in the country, unless ruled otherwise in an international agreement to which the Republic of Bulgaria is a party.

(6) Where the mandatory insurance under Paragraph (5) is made upon the entry into the country, the general terms and conditions, the minimum insurance amount, the minimum insurance premium and the procedure shall be set out in regulations issued by the Council of Ministers.

(7) (Amended, SG No. 32/2022, effective 26.04.2022) The regulations of Paragraphs (4) – (6) shall not apply to foreigners residing in the Republic of Bulgaria on a long or short term basis to whom shall apply the regulations for coordination of the social security systems within the meaning of Item 22 of § 1 of the Supplementary Provisions of the Health Insurance Act.

(8) The procedures for access to medical aid in the Republic of Bulgaria of the persons under Paragraph (7) shall be set out by the regulations under Article 81 (3).

Article 83a

(New, SG No. 1/2014, effective 3.01.2014)

(1) The methods and technologies established in medical science and practice, as well as the medical standards approved pursuant to Article 6(1) of the Medical-Treatment Facilities Act and the Rules of Good Medical Practice adopted and approved pursuant to Article 5(4) of the Doctors' and Doctors of Dental Medicine Professional Organisations Act applicable also to Bulgarian citizens

shall apply to the citizens of another Member State of the European Union who are provided health services in Bulgaria under Chapter Two, Section XII of the Health Insurance Act.
(2) The persons under paragraph 1 shall pay the value of the health services provided to them to the medical treatment facility and the medical treatment facility shall issue a detailed financial report on the financial resources spent.
(3) Medical treatment facilities providing health services to citizens of other Member States of the European Union shall not set health service prices different from those applicable to Bulgarian citizens.

Section II
Patient's Rights and Obligations

Article 84
(1) Patient is any person who has sought or who is receiving medical aid.
(2) Persons shall be registered as patients with their informed consent, except for the cases prescribed by law.

Article 85
(Amended, SG No. 41/2009, effective 2.06.2009)
Patients shall be provided with medical care regardless of their age, gender, origin, language, national, racial or political appurtenance, education, beliefs, cultural level, sexual orientation, personal, social or material status and cause of disease.

Article 86
(1) In the capacity of a patient, every person shall be entitled to:
1. respect for their civil, political, economic, social, cultural and religious rights;
2. care from the community in which they live;
3. accessible and high-quality medical aid;
4. more than one medical opinion on the diagnosis, treatment and prognosis of the disease;
5. protection of the data related to their health status;
6. remuneration for the work they perform equal to the one they would receive if healthy;
7. becoming aware of their rights and obligations in a language comprehensible to him/her;
8. clear and accessible information on their health status and the methods of their possible treatment;
9. (new, SG No. 41/2009, effective 2.06.2009) health prevention and rehabilitation;
10. (new, SG No. 41/2009, effective 2.06.2009) reliability and safety of diagnostic and medical procedures carried out in the course of therapy;
11. (new, SG No. 41/2009, effective 2.06.2009) access to state-of-the-art treatment methods;
12. (new, SG No. 41/2009, effective 2.06.2009) prevention of pain and suffering during treatment, as far as possible;
13. (new, SG No. 41/2009, effective 2.06.2009) access to medical records relating to their health status.
(2) In the case of hospitalisation, patients shall be entitled to:
1. visits by the family doctor and the specialists who has issued the hospitalisation instruction;
2. (new, SG No. 60/2011, effective 5.08.2011, amended, SG No. 54/2012 SG No. 15/2013, effective 1.01.2014) have the medical treatment facilities for in-patient health care arrange the supply of any medical devices, required for his/her treatment, if they would not be financed by the National Health Insurance Fund or the state budget;
3. (renumbered from Item 2, SG No. 60/2011, effective 5.08.2011) access to state-of-the-art treatment methods;
4. (renumbered from Item 3, SG No. 60/2011, effective 5.08.2011) the services of a psychotherapist, a lawyer and a priest;
5. (renumbered from Item 4, SG No. 60/2011, effective 5.08.2011) education and access to activities meeting their social, religious and cultural needs;

6. (amended, SG No. 41/2009, effective 2.06.2009, renumbered from Item 5, SG No. 60/2011, effective 5.08.2011) information on the price of each medical service, manipulation, treatment and medicinal products in the primary and hospital care.
(3) (New, SG No. 60/2011, effective 5.08.2011, amended, SG No. 54/2012) In the cases under Paragraph (2), Item 2 the medical devices shall be supplied and paid for under the procedure of Article 82b.
(4) (Renumbered from Paragraph 3, SG No. 60/2011, effective 5.08.2011) The patient's rights shall be exercises, while observing the rules for the structure, activities and internal order of the medical establishment.

Article 86a

(New, SG No. 41/2009, effective 2.06.2009)
(1) A Public Patient Advocacy Council with the Minister of Health shall be established.
(2) (Amended, SG No. 101/2009, effective 18.12.2009) The Public Patient Advocacy Council shall be composed of seven representatives of representative patient advocacy organisations within the meaning of Article 86b, one representative from an organisation of people with disabilities who is a member of the National Council for Integration of People with Disabilities, one representative of an organisation for people with disabilities who is a member of the National Council for Integration of People with Disabilities, and one representative each for the Ministry of Health, for the Ministry of Labour and Social Policy, for NHIF, for the Bulgarian Medical Association, for the Bulgarian Dental Association, for the Bulgarian Pharmaceutical Association and for the Bulgarian Association of Health Care Professionals.
(3) The Public Patient Advocacy Council shall be an advisory body with the following functions:
1. monitoring and analysis of all activities relating to patient rights;
2. preparation of annual reports on issues concerning patient rights and their submission to the Minister of Health;
3. analysis of the implementation of legislation on patient rights and preparation of proposals on its amendment and supplementation which shall be provided to the Minister of Health;
4. discussion and issuance of opinions on bills for legislative acts relating to patient rights.
(4) The organisation and the activities of the Public Patient Advocacy Council shall be laid down in rules of procedure drawn up by the Public Patient Advocacy Council and endorsed by the Minister of Health.

Article 86b

(New, SG No. 101/2009, effective 18.12.2009)
(1) Representative patient advocacy organisations shall be organisations which meet the following conditions:
1. aimed at protecting rights and interest of all patients regardless of any particular disease, diagnosis or suffering;
2. registered as non-profit public-interest associations within the meaning of the Non-Profit Legal Persons Act;
3. be nationally represented, with regional structures operating throughout Bulgaria
(2) The managing bodies of the associations referred to in Paragraph 1 may not include government officials; local government or administration officials; employees of the National Health Insurance Fund; medical care providers; members of managing and supervisory bodies of manufacturers, importers and traders of medicinal products, medical devices and equipment.
(3) The Ministry of Health and other government authorities, the local government and local administration, as well as the National Health Insurance Fund shall assist the patient advocacy associations. These associations shall be entitled to:
1. obtain information about draft legislative acts pertaining to rights and interest of patients;
2. notify the competent authorities about cases of violated patients' rights; require information about any inspections conducted, respective results thereof and measures undertaken accordingly.

(4) Organisations under Paragraph 1 may participate, by way of representatives, in the work of consultative bodies, committees and task forces at the Ministry of Health and the National Health Insurance Fund.

Article 86c

(New, SG No. 101/2009, effective 18.12.2009)

(1) Patient advocacy organisations shall be recognised as being representative within the meaning of Article 86b(1) by the Minister of Health upon their request.

(2) The recognition of patient advocacy organisations as being representative under Paragraph 1 shall be effected as per a procedure and criteria laid down in an ordinance by the Minister of Health.

(3) (Supplemented, SG No. 77/2018, effective 1.01.2019) Any refusal by the Minister of Health to recognise a patient advocacy organisation as being representative may be appealed before the relevant Administrative Court as per the procedure laid down in the Code of Administrative Procedure.

(4) Every three years following their relevant recognition as per Paragraph 1, patient advocacy organisations shall verify their representative status as per a procedure laid down in the ordinance referred to in Paragraph 2.

(5) The Minister of Health may conduct compliance inspections pertaining to the requirements of Article 86b(1) in respect of each representative patient advocacy organisation. Depending on the inspection results, the Minister of Health may, by order, confirm or revoke the representative status of a given organisation. Compliance inspections shall be conducted as per a procedure laid down in the ordinance referred to in Paragraph 2.

(6) Any order issued by the Minister of Health for the purpose of revoking a patient advocacy organisation's representative status may be appealed as per the procedure laid down in Paragraph 3.

Article 87

(1) Medical activities shall be performed upon the informed consent expressed by the patient.

(2) Where the patient is a young person or has been put under partial legal incapacity, his/her informed consent shall be given together with the consent of a parent or a custodian.

(3) (New, SG No. 41/2009, effective 2.06.2009) The consent of parents or custodians required under Paragraph (2) shall not be necessary where health consultations, preventive examinations and tests of persons over the age of 16 are being performed. The specific types of consultation activities, preventive examinations and tests shall be laid down in an ordinance to be issued by the Minister of Health.

(4) (Renumbered from Paragraph 3, SG No. 41/2009, effective 2.06.2009) Where the patient is a child or has been put under full legal incapacity, the informed consent shall be given by a parent or a custodian, unless prescribed otherwise by law.

(5) (New, SG No. 41/2009, effective 2.06.2009) Where the consent of a parent, guardian or custodian referred to in Paragraphs (2) and (4) cannot be received for a child or young person who has been accommodated outside their family by an order of the court, informed consent shall be given by a person entrusted with raising the child once the Social Assistance Directorate has issued a positive opinion.

(6) (New, SG No. 41/2009, effective 2.06.2009) Where the young person or child has been temporarily accommodated pursuant to the administrative procedures provided for in Article 27 of the Child Protection Act, the informed consent referred to in Paragraph (5) shall be given by the Social Assistance Directorate.

(7) (Renumbered from Paragraph 4, SG No. 41/2009, effective 2.06.2009) In the case of persons with mental who have been found incapable of giving informed consent, the latter shall be expressed by the persons under Article 162, Paragraph (3).

Article 88

(1) (Supplemented, SG No. 41/2009, effective 2.06.2009) In order to obtain the informed consent, the treating physician (doctor of dental medicine) shall inform the patient or the parent, custodian or

guardian, the person referred to in Article 87 (5), the directorate referred to in Article 87 (6), respectively, as well as the persons under Article 162 (3) about:
1. the diagnosis and nature of the disease;
2. the description of the goals and the nature of the treatment, the reasonable alternatives, the expected outcome and the prognosis;
3. the potential risks related to the proposed methods of diagnostics and treatment, including the side effects and adverse reactions, pain and other discomfort;
4. the likelihood of a favourable impact, and the health risk in the application of other methods of treatment or in the refusal to take treatment.
(2) (Supplemented, SG No. 41/2009, effective 2.06.2009) The medical information under Paragraph (1) shall be provided to the patient or the parent, custodian or guardian the person referred to in Article 87 (5), the directorate referred to in Article 87 (6), respectively, as well as the persons under Article 162 (3) in a timely manner and in an appropriate amount and format to ensure the freedom of choice of a treatment.

Article 89

(1) In the event of surgical intervention, general anaesthetics, invasive and other diagnostic and therapeutic methods leading to higher risk the patient's life of health or temporary change of the mind, the information under Article 88 and the informed consent shall be given in writing.
(2) The activities under Paragraph (1) may be performed to the benefit of the patient's health without any informed consent given in writing only if there is an immediate threat to the patient's life and:
1. his/her physical or mental condition prevent him/her from expressing an informed consent;
2. (supplemented, SG No. 41/2009, effective 2.06.2009) it is impossible to obtain the consent of the parent, custodian, guardian, the person referred to in Article 87 (5), the directorate referred to in Article 87 (6), or the person under Article 162 (3) in a timely manner, where such a consent is required by law.
(3) With regard to persons have mental disorders and are incapable of giving informed consent, the activities under Paragraph (1) may be performed only with the permission of the commission for medical ethics and upon obtaining the consent of their legitimate representatives or the head of the medical establishment, where no such commission exists.

Article 90

(1) (Supplemented, SG No. 41/2009, effective 2.06.2009) The patient or the parent, custodian or guardian, the person referred to in Article 87 (5), the directorate referred to in Article 87 (6), respectively, as well as the persons under Article 162 (3) may refuse the medical aid offered or continuation of medical activities that have started at any point of time.
(2) The refusal under Paragraph (1) shall be certified in the medical records with signatures of the person.
(3) (Supplemented, SG No. 41/2009, effective 2.06.2009) Where the patient or the parent, custodian or guardian the person referred to in Article 87 (5), the directorate referred to in Article 87 (6), respectively, or the person under Article 162 (3) in not in a position or refuses to certify the refusal under Paragraph (1) in writing, this fact shall be certified with the signature of the treating physician and a witness.
(4) (Amended, SG No. 41/2009, effective 2.06.2009) Where there is refusal under Paragraph (1) and the patient's life is threatened, the head of the medical establishment may decide to apply life-saving treatment.
(5) (New, SG No. 41/2009, effective 2.06.2009) Patients may decide to withdraw their consent under Paragraph (2) at any time and in this case medical specialists shall not be liable for any potential delays in the diagnostic and treatment process.

Article 91

Medical aid may be provided to the patient against his/her will only in cases prescribed by law.

Article 92

(1) The treating physician shall inform the patient about:

1. his/her health condition and the need for treatment;
2. the disease in connection with which the patient has sought medical aid, and its prognosis;
3. the planned preventive, diagnostic, therapeutic and rehabilitation activities, as well as the related risks;
4. the diagnostic and therapeutic alternatives;
5. the name, position and specialty of the persons involved in the diagnostic and therapeutic process.

(2) (Amended, SG No. 41/2009, effective 2.06.2009) Patients shall be entitled to refuse to be informed as provided for in Items 2 and 3 of Paragraph (1) except where their medical condition represents a threat to the health of others.

(3) The decision under Paragraph (2) shall be reflected in writing in the patient's medical records.

(4) (New, SG No. 41/2009, effective 2.06.2009) Patients shall be entitled to authorise in writing a person who is to be informed instead.

Article 93

(1) (Amended and supplemented, SG No. 41/2009, effective 2.06.2009, amended, SG No. 98/2010, effective 1.01.2011) The patient or the parent, guardian or custodian, the person referred to in Article 87 (5), the directorate referred to in Article 87 (6), respectively, or a person authorised by them may submit complaints and alerts to RHI in the case of violation of the patient's rights under this Act or disputes related to medical services.

(2) (Amended, SG No. 98/2010, effective 1.01.2011) The respective RHI shall conduct ex officio an inspection concerning the complaint or alert within seven days.

(3) (Amended, SG No. 98/2010, effective 1.01.2011) Where an administrative violation is observed, the RHI inspecting officer shall draw up a statement of findings, while the RHI director shall issue a penalty order under the Administrative Violations and Sanctions Act.

(4) (Amended, SG No. 98/2010, effective 1.01.2011) Where the established violations are punishable under the Doctors and Dentists Professional Organisations Act and the Health Insurance Act, the RHI shall inform and send the complaint to the regional association of the Bulgarian Medical Association and the Bulgarian Dental Association and the Regional Health Insurance Fund.

(5) (Amended, SG No. 98/2010, effective 1.01.2011) Within three days of the end of the check, the RHI shall advise the patient of the results thereof and the action undertaken.

Article 94

The patient shall:

1. take care of his/her own health;
2. not harm the health of others;
3. assist the providers of medical aid in the performance of the activities related to the improvement and recovery of his/her health;
4. observe the order established at healthcare and medical treatment facilities.

Article 95

(1) In the case of incurable diseases with unfavourable prognosis, the patient shall be entitled to palliative medical care.

(2) The objective of palliative medical care shall be to maintain the quality of life through reduction or elimination of some immediate signs of the diseases, as well as the related adverse psychological and social effects.

Article 96

(1) Palliative medical care shall include:

1. medical surveillance;
2. healthcare aimed at providing care to the patient, removing pain and the psychological and emotional effects of the disease;

3. moral support to the patient and his/her relatives.
(2) (Amended, SG No. 59/2010, effective 31.07.2010) Palliative medical care shall be provided by the family doctor, by medical treatment facilities for out-patient and in-patient health care and by dispensaries.
(3) The requirements to the provision of palliative medical care shall be set out in regulations issued by the Minister of Health.

Article 97

No euthanasia shall be applied within the territory of Bulgaria.

Article 98

(1) Persons who died at a medical treatment facility shall be subject to post-mortem upon notification of a parent, adult child, spouse or sibling.
(2) (New, SG No. 98/2010, effective 14.12.2010) Post-mortem shall also be performed in case of death of a child placed outside the family home as per the procedure laid down in the Child Protection Act.
(3) (Renumbered from Paragraph 2, SG No. 98/2010, effective 14.12.2010) Post-mortem of persons who died outside a medical treatment facility may be performed at the request of the medical doctor who reported the death or at the explicit request of the relatives of the deceased person.
(4) (Renumbered from Paragraph 3, supplemented, SG No. 98/2010, effective 14.12.2010) Upon the explicit request of the relatives of the deceased the head of the medical treatment facility may issue a post-mortem exemption order in the circumstances under Paragraph 1.
(5) (New, SG No. 98/2010, effective 14.12.2010) Upon the explicit write request of a parent, custodian or guardian, the head of the medical treatment facility may issue a post-mortem exemption order in the circumstances under Paragraph 2 only if the child passed away at a medical treatment facility for in-patient care.
(6) (Renumbered from Paragraph 4, SG No. 98/2010, effective 14.12.2010) Post-mortem shall not be performed when the corpse is subject to forensic expertise.

Section III
Medical Aid in Emergency

Article 99

(1) The government shall organise and finance a system for emergency medical aid.
(2) Emergency is an acute or sudden change of human health, which requires urgent medical aid.
(3) Medical aid in emergency shall be aimed at preventing:
1. death;
2. severe or irreversible morphological and functional damage to vital organs and systems;
3. complications in women at childbirth, which threaten the health and life of the mother or the foetus.

Article 100

(1) Each person on the site of the accident shall inform the nearest emergency medical aid centre, another medical establishment or police department.
(2) Each medical establishment shall provide the possible volume of medical activities to a patent in emergency, regardless of his/her citizenship, address or health insurance status.
(3) Where it is impossible to provide the necessary volume of activities, the patient shall be accommodated at the nearest medical establishment which has the requisite conditions, provided that the condition of the patient allows doing so.
(4) In the case of relocation of a patient from one medical establishment to another, all medical records on the diagnostic, consultative and therapeutic activities shall be attached in the summarized form of a medical discharge report.
(5) A patient shall not be transported if the transportation or the related circumstances lead to unjustified high risk for his/her health and life.

Section IV
Medical Expert Activities

Article 101

(Amended, SG No. 41/2009, effective 1.07.2009)

(1) (Supplemented, SG No. 59/2010, effective 31.07.2010) Medical expert examination shall be performed with a view to establishing short-term incapacity for work, the type and extent of disability of children up to the age of 16 years and of persons eligible for length of service and old age pension pursuant to Article 68 of the Social Insurance Code and with a view to establishing the extent of long-term limited capability for work of persons of working age, as well as to confirm occupational disease.

(2) (Amended, SG No. 98/2010, effective 1.01.2011) Medical expert examinations shall be organised and guided by the Minister of Health and by the RHI.

(3) (New, SG No. 59/2010, effective 31.07.2010) When conducting medical expert examination to establish short-term incapacity for work an assessment shall also be made whether the health condition of the person prevents him/her from appearing before the investigating authorities or before the Judiciary, when such appearing before the said authorities is necessitated during the short-term incapacity for work.

(4) (Renumbered from Paragraph 3, SG No. 59/2010, effective 31.07.2010) The type and extent of disability and the extent of long-term limited capability for work shall be expressed as percentage of the ability of a healthy person.

(5) (Renumbered from Paragraph 4, SG No. 59/2010, effective 31.07.2010) The type and extent of disability of people eligible for length of service and old age pension pursuant to Article 68 of the Social Insurance Code shall be established for life. Re-assessment of such persons may be performed at their request or at the request of the medical expert control authorities.

(6) (Renumbered from Paragraph 5, SG No. 59/2010, effective 31.07.2010) For the persons referred to in Paragraph (4) who work, the extent of long-term limited capability for work shall be determined, if the type and extent of disability have not been established.

(7) (Renumbered from Paragraph 6, amended, SG No. 59/2010, effective 31.07.2010) The principles and criteria for medical expert examination, the procedure for establishing the short-term incapacity for work, the type and extent of long-term limited capability for work and confirming occupational disease, as well as the conditions and the procedure for conducting medical expert examination under Article 103, paragraph 3 shall be laid down in an ordinance to be issued by the Council of Ministers.

Article 101a

(New, SG No. 98/2010, effective 14.12.2010)

(1) The validity period of the decision concerning the level of long-term limited capacity for work shall be determined in the regulations under Article 101(7), depending on the nature of the impairment, the dynamics of the disability progression and the possibilities to recover.

(2) In the case of definitive conditions specified in the regulations under paragraph 1 which will not enable the full or partial recovery, the level of long-term limited capacity for work shall be determined for life.

(3) In the case of multiple impairments, some of which are not definitive, the validity period of the decision concerning the level of long-term limited capacity for work shall be determined under paragraph 1.

Article 101b

(New, SG No. 8/2023)

(1) The regional health inspectorate shall notify officially the persons of the need for regular re-assessment not later than four months before the expiration of the period of long-term limited capacity for work/type and extent of disability defined in the expert decision.

(2) Where persons have submitted an application statement for re-assessment not later than three months before the expiry of the term of validity of their expert decisions and the TMEP has not

established the type and extent of disability/the level of long-term limited capacity for work based on the application, there is a delay in the medical expert examination and the validity of the last issued expert decision shall be extended until a new expert decision is issued.
(3) By the 20th day of the month, information about the delay in the medical expert examination and about the scheduled date for re-assessment in the cases covered by Paragraph (2) shall be sent by the regional health inspectorates to the interested bodies - the NSSI, the NHIF, the Social Assistance Agency, the Agency for People with Disabilities, the National Revenue Agency and the municipality at the current address of the person. In the cases where there is no scheduled date, the structures of the relevant regional health inspectorate shall send information about the specified date later.
(4) At the request of the person being re-assessed, the regional health inspectorates shall send information about the existence of a delay in the medical expert examination, about the scheduled date for re-assessment to insurers or other bodies and organisations for the purpose of exercising rights during the extended period of disability in the issued expert decisions of TMEP and NMEP.
(5) The medical documentation of the persons who have submitted an application statement for re-assessment and, after having been regularly summoned, have failed not appear for an examination at the TMEP, shall be returned to the Regional Medical Expert Record Offices, and the extension of the term of validity the expert decision pursuant to Paragraph (2) shall be considered terminated from the date of the person's failure to appear; the interested persons and authorities referred to in Paragraphs (3) and (4) shall be notified of this within fourteen days in order to terminate the rights and the support arising from the expert decision.

Article 102

(1) The National Medical Expert Board shall be established at Council of Ministers with the following powers:
1. to prepare and submit to the Council of Ministers opinions on the national health policy in connection with medical expert activities;
2. to ensure the coordination of government authorities in connection with medical expert activities;
3. to analyse the information on the performance, development and condition of medical expert activities in this country;
4. to draft and submit for adoption to the Council of Ministers new and amending bills related to medical expert activities;
5. to develop a methodology for financing and control of medical expert bodies, which shall be adopted by the Council of Ministers.
(2) (Amended, SG No. 41/2009, effective 2.06.2009, SG No. 62/2010, effective 10.08.2010) The National Medical Expert Board shall have the following membership: a Deputy Prime Minister who will serve as the chairperson of the Board, the Minister of Health, the Minister of Labour and Social Policy, the Minister of Finance, the head of the National Social Security Institute (NSSI), the NHIF Manager, the NMEP director and the executive director of the Agency for People with Disabilities.
(3) The structure and activities of the Board under Paragraph (1) shall be set out in regulations issued by the Council of Ministers.

Article 103

(1) (Amended, SG No. 41/2009, effective 1.07.2009) Medical expert examination shall include an expert examination of short-term incapacity for work, expert examination of the type and extent of disability and expert examination of long-term limited capability for work.
(2) The medical expert opinions and reports on the short-term incapacity for work shall be given by the treating physician, Medical Advisory Committees (MAC), Territorial Medical Expert Panels (TMEP) and NMEP.
(3) (New, SG No. 59/2010, effective 31.07.2010) Assessment of a person's ability to appear before the investigating authorities or before the Judiciary shall be made by MAC, by the urgent medical aid centres, by TMEP and by NMEP. The said assessment shall be certified by expert decision - "Medical certificate", in a form established by the Minister of Health and by the Minister of Justice.

(4) (Supplemented, SG No. 41/2009, effective 1.07.2009, renumbered from Paragraph 3, SG No. 59/2010, effective 31.07.2010) Expert examination of the type and extent of disability, the extent of long-term limited capability for work and occupational diseases shall be performed by TMEP and NMEP.
(5) (Amended, SG No. 41/2009, effective 1.07.2009, renumbered from Paragraph 4, SG No. 59/2010, effective 31.07.2010, amended, SG No. 40/2012) Expert examination of the type and extent of disability for children up to the age of 16 years shall be performed by TMEP and NMEP with the participation of paediatricians.
(6) (New, SG No. 8/2023) The deadline for carrying out the expert examination is three months of the submission of the application statement in the Regional Medical Expert Record Office or three months of the receipt of the complaint at the NMEP.

Article 103a

(New, SG No. 106/2013, effective 1.12.2014)
The medical expert evaluation authorities shall submit to the National Social Security Institute the data contained in the sick leave certificates issued, and the judgements related to any appeals against them in accordance with a procedure defined in an instrument of the Council of Ministers.

Article 104

(1) (Amended, SG No. 98/2010, effective 1.01.2011) Medical Advisory Committees shall be instituted and wound up by order of RHI directors at medical treatment facilities for out-patient and in-patient health care, upon the proposal of the head of the respective medical treatment facility.
(2) At the medical treatment facilities under Article 5 (1) of the Medical Treatment Facilities Act and at university hospitals, the membership of MAC shall be set out in an order of the head of the respective medical establishment.
(3) Medical Advisory Committees shall be general and specialised. The membership of MAC shall include at least two permanent members who are medical doctors who hold a recognised specialism, including one chairperson.

Article 104a

(New, SG No. 41/2009, effective 1.07.2009, amended, SG No. 98/2010, effective 1.01.2011, repealed, SG No. 40/2012).

Article 105

(1) (Amended, SG No. 59/2010, effective 31.07.2010, SG No. 98/2010, effective 1.01.2011) Territorial Medical Expert Panels shall be instituted and wound up by order of RHI directors, in consultation with the Minister of Health, at state-owned and municipal medical treatment facilities for in-patient health care, mental health centres, dermal and venereal disease centres, and comprehensive oncology centres.
(2) Territorial Medical Expert Panels shall be structural units of the medical treatment facilities at which they have been instituted.
(3) (Amended, SG No. 41/2009, effective 1.07.2009, repealed, SG No. 100/2010, effective 1.01.2012).

Article 106

(1) (Amended, SG No. 41/2009, effective 1.07.2009) The membership of TMEP and NMEP shall include medical doctors who hold a recognised specialty and have at least 5 years of service in the medical field.
(2) (Repealed, SG No. 18/2018, effective 27.02.2018).
(3) (Amended, SG No. 41/2009, effective 1.07.2009, SG No. 40/2012, SG No. 18/2018, effective 27.02.2018) When a medical expert examination is performed, a medical doctor may not be involved:
1. who has been involved in the preparation of the expert decision appealed against;

2. who has been involved in the consultative work relating to the expert examination of the temporary incapacity for work, the type and extent of the disability and the long-term limited capability for work of the person assessed;
3. who is a spouse, a lineal relative without limitations or a collateral consanguineal relative up to two times removed from the person assessed;
4. who is a cohabiting (common law) partner of the person assessed.
(4) (New, SG No. 18/2018, effective 27.02.2018) In the cases specified in Paragraph (3), the medical doctor participating in the TMEP or NMEP shall be obliged to declare in writing that he/she wishes to be removed from participation in the meeting of the relevant panel.
(5) (New, SG No. 18/2018, effective 27.02.2018) The person assessed can also request the removal of a medical doctor from participation in a meeting in the cases specified in Paragraph (3).
(6) (New, SG No. 18/2018, effective 27.02.2018) The filing procedure and the standard form of the request under Paragraphs (4) and (5) shall be determined in the regulations under Article 109.
(7) (New, SG No. 18/2018, effective 27.02.2018) Upon receiving a request for removal of a medical doctor in the cases specified in Paragraphs (4) and (5), the head of the medical treatment facility or the director of NMEP shall be obliged to rule on its grounds within three days of its receipt.
(8) (New, SG No. 18/2018, effective 27.02.2018) In the event that the request for removal is justified, an alternate member of the TMEP or a medical doctor from the other specialised NMEP divisions designated by the head of the medical treatment facility or by the director of NMEP shall be included in the performance of the medical expert examination.
(9) (New, SG No. 18/2018, effective 27.02.2018) A request under Paragraphs (4) and (5) can also be filed by electronic means under the conditions and in accordance with the procedure established by the Electronic Document and Electronic Trust Services Act and the Electronic Government Act.

Article 107

(1) (Supplemented, SG No. 41/2009, effective 1.07.2009, amended, SG No. 40/2012) The director of the medical establishment shall sign a funding agreement for the activities of TMEP with the Minister of Health.
(2) (Supplemented, SG No. 41/2009, effective 1.07.2009, amended, SG No. 40/2012) Highly specialised and costly medical and diagnostic tests related to the process of medical expert examination of the capability for work, which are performed at the request of TMEP and NMEP, shall be financed by NHIF within the framework of its annual budget.

Article 108

(1) (Supplemented, SG No. 41/2009, effective 1.07.2009, amended, SG No. 40/2012) The activities related to the registration, processing and storage of health information for persons assessed by TMEP and NMEP shall be carried out by Regional Medical Expert Record Offices (RMERO).
(2) (Amended, SG No. 98/2010, effective 1.01.2011) The Regional Medical Expert Record Offices shall be structural units of RHI.
(3) (Amended, SG No. 41/2009, effective 1.07.2009, SG No. 40/2012) The medical records of persons assessed by TMEP and NMEP whose disability has been determined as per type and extent and whose percentage of long-term limited capability for work has been estimated shall be stored for 40 years of the date of the latest decision of TMEP and NMEP and that of all other persons shall be stored for five years.
(4) (Amended, SG No. 41/2009, effective 1.07.2009, SG No. 98/2010, effective 1.07.2011, SG No. 40/2012, SG No. 85/2017) Copies of the decisions of TMEP and NMEP shall be sent to the National Health Information Centre and the Agency for People with Disabilities electronically, while complying with the conditions and procedures laid down in the Electronic Document and Electronic Trust Services Act, as well as the Electronic Government Act.

Article 108a

(New, SG No. 102/2018, effective 1.01.2019)

(1) The National Medical Expert Panel shall establish and maintain an information database of all persons who have passed through TMEP/NMEP to have their long-term limited capability for work/type and degree of disability established.
(2) The information database referred to in Paragraph 1 shall contain:
1. (new, SG No. 103/2020, effective 4.12.2020) application-declaration for assessment/re-assessment;
2. (renumbered from Item 1, SG No. 103/2020, effective 4.12.2020) document referring the patient for assessment of their long-term limited capability for work/type and degree of disability (medical protocol/medical referral);
3. (renumbered from Item 2, SG No. 103/2020, effective 4.12.2020) expert decision;
4. (renumbered from Item 3, SG No. 103/2020, effective 4.12.2020) diagnosis of the underlying (primary) disease;
5. (renumbered from Item 4, SG No. 103/2020, effective 4.12.2020) diagnosis of accompanying (concomitant) diseases;
6. (renumbered from Item 5, SG No. 103/2020, effective 4.12.2020) all medical-diagnostic activities performed that are relevant to the assessment of the long-term limited capability for work/type and degree of disability;
7. (renumbered from Item 6, SG No. 103/2020, effective 4.12.2020) the examinations carried out by a doctor, which are relevant to the assessment of the long-term limited capability for work/type and degree of disability;
8. (renumbered from Item 7, SG No. 103/2020, effective 4.12.2020) other data relevant to the long-term limited capability for work/type and degree of disability.
(2a) (New, SG No. 105/2020, effective 1.07.2022 - amended, SG No. 8/2022, effective 1.01.2022, SG No. 18/2022, effective 1.04.2022) In the information database referred to in Paragraph 1 shall be entered also the medical documents issued by the Medical Advisory Committees TMEP or NMEP according to Article 73(1) of the Persons with Disabilities Act.
(3) (Supplemented, SG No. 103/2020, effective 4.12.2020, SG No. 41/2022, effective 3.06.2022) The purpose of the information database referred to in Paragraph (1) is to collect, process, store and analyse the data regarding the persons specified in Paragraph (1) in order to use said data for conducting medical expertise activities, planning of activities related to the satisfaction of the needs of said persons for education, medical and social rehabilitation, employment status as well as for assessing the health status of the population and controlling the medical expertise activities.
(4) (Amended, SG No. 103/2020, effective 4.12.2020) The medical expert examination authorities, the Regional Medical Expert Record Offices, the National Health Insurance Fund, the National Social Security Institute and the persons wishing to be assessed/re-assessed shall provide the information required to create and maintain the database referred to in Paragraph 1.
(5) (Amended, SG No. 103/2020, effective 4.12.2020) The information in the database shall be entered and used for the purposes specified in Paragraph 3.
(6) The Ministry of Health, the National Health Insurance Fund, the Ministry of Education and Science, the National Social Security Institute, the Social Assistance Agency, 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 Centre of Public Health and Analyses, the Directorate General for Civil Registration and Administrative Services and other authorities that conduct activities in the field of people with disabilities shall have the right to access the database.
(7) (New, SG No. 103/2020, effective 4.12.2020) The person being assessed and his/her legal representatives/proxies shall have the right of access to the health information of said person in the information database referred to in Paragraph 1.
(8) (Renumbered from Paragraph 7, supplemented, SG No. 103/2020, effective 4.12.2020) The conditions and procedure for keeping and maintaining the database referred to in Paragraph 1 and the type of the information as well as the access to it shall be laid down in the regulations referred to in Article 109.

Article 109

The structure and activities of the medical expert bodies under Article 103 and of RMERO shall be set out in regulations issued by the Council of Ministers.

Article 110

(Amended, SG No. 98/2010, effective 1.01.2011)

Medical expert activities shall be subject to control by the National Medical Expert Board, the Minister of Health, the Minister of Labour and Social Policy, NHIF, NSSI, the regional boards under Article 111, and RHIs.

Article 111

(1) (Supplemented, SG No. 59/2010, effective 31.07.2010, amended, SG No. 98/2010, effective 1.01.2011) For the purpose of exercising control over the instruments issued by medical expert bodies with regard to short-term incapacity for work, a regional board shall be set up by order of the director of the respective RHI. Regional boards shall include representatives of the RHI, the NSSI regional office, and the RHIF. The regional board shall also conduct random inspections ex officio of at least two percent of the decisions on short-term incapacity and expert decisions under Article 103(3) issued within the territory of the respective region.

(2) The regional board shall review and control medical expert activities with regard to short-term incapacity for work, which are carried out by treating physicians, MAC and TMEP. The organisation of the activities of the board shall be set out in regulations issued by the Minister of Health together with the NSSI head.

(3) Regional boards shall check the observance of the requirements for the issuance of decisions on short-term incapacity for work by treating physicians and TMEP at the proposal of the parties and organisations concerned (assessed persons, insurers, NSSI and NHIF territorial subdivisions).

(4) Where a violation is observed in the issuance of expert decisions on short-term incapacity for work, the regional board shall advise in writing the higher-standing medical expert body and the parties and organisations concerned (assessed persons, insurers, NSSI and NHIF territorial subdivisions).

Article 112

(1) (Amended, SG No. 41/2009, effective 1.07.2009) The appeals and objections on part of the parties and organisations concerned (assessed persons, insurers, NSSI, the Social Assistance Agency, the Agency for People with Disabilities and the bodies for medical expert examination of the capability for work) shall be served:

1. to the Medical Advisory Committee within 14 days of their receipt where these are against the decisions of the treating physician;

2. (supplemented, SG No. 59/2010, effective 31.07.2010) to TMEP within 14 days of their receipt where these are against the decisions of MAC and the urgent medical aid centres;

3. (amended, SG No. 41/2009, effective 1.07.2009, SG No. 40/2012) to NMEP within 14 days of their receipt where these are against the decisions of TMEP;

4. (amended, SG No. 30/2006, effective 1.03.2007, in respect of the replacement of the words "Sofia City Court" with "Administrative Court Sofia - city", SG No. 104/2013, effective 4.01.2014) to the administrative court at the permanent or the current address of the appellant pursuant to the Code of Administrative Procedure where these are against the decisions of NMEP.

(2) The parties and organisations concerned (assessed persons, insurers, NSSI and NHIF territorial subdivisions) may appeal, within 14 days, against decisions of MAC violating the requirements and procedure for the issuance of expert decisions on short-term incapacity for work also before the regional board under Article 111.

(3) The regional board shall rule on the appeals within ten days of the repeated medical expert examination and report on short-term incapacity for work, which shall be performed by a specialised MAC designated by the board, depending on the type of disease.

(4) Where a violation is observed in the issuance of the appealed expert decision, the regional board shall revoke it and the capability for work shall be established in the repeated medical expert examination.
(5) The decision of the regional board to revoke the medical expert decision and the decision of the repeated expert examination shall be sent to the parties concerned (assessed persons, insurers and NSSI) and RHIF.
(6) An appeal against a decision of MAC under Paragraph (2) shall be an obstacle to appealing against it under Item 2 of Paragraph (1).
(7) The decision of the regional board not to grant the appeal shall not prevent the appeal against the decision of MAC before TMEP under Item 2 of Paragraph (1). In these cases, time limits shall start on the date of receipt of the decision of the regional board.
(8) The decision of the repeated expert examination shall be subject to appeal under Item 2 of Paragraph (1).
(9) (New, SG No. 41/2009, effective 1.07.2009, amended, SG No. 8/2023) Appeals pursuant to Paragraphs (1) to (8) against expert decisions on long-term limited capability for work/type and extent of disability issued by the medical expert bodies shall not suspend the enforcement of these decisions. During the period of appeal against expert decisions on long-term limited capability for work/type and extent of disability the person shall enjoy the rights arising from the appealed expert decision, and in the event that the type and extent of disability is reduced and this leads to a reduction or elimination of the support granted, the reassessed person shall not reimburse the extra amount received.
(10) (New, SG No. 59/2010, effective 31.07.2010) The expert decisions referred to in Article 103, paragraph 3 shall be appealed pursuant to the procedure set forth in paragraph 1, items 2, 3 and 4, paragraphs 2 - 8 by the parties concerned and by the investigating authorities or by the Judiciary.
(11) (New, SG No. 98/2016, effective 1.01.2017) For the National Social Security Institute, the time-period under Paragraph 1, Items 1 and 2 shall start from the receipt of the data from the issued sickness certificates in accordance with the procedure established by the Ordinance on the submission to the National Social Security Institute of the data from issued sickness certificates and decisions regarding their appeal (SG No. 67 of 2014), but not earlier than the submission of certificates under Article 8, Paragraph 1 and Article 11, Paragraph 1 of the Ordinance on cash benefits and benefits from the public social security (promulgated, SG No. 57 of 2015; amended, SG No. 17 of 2016).

Article 112a

(New, SG No. 98/2010, effective 1.07.2011, amended, SG No. 40/2012, SG No. 85/2017, supplemented, SG No. 103/2020, effective 4.12.2020) The organisations concerned (the NSSI, the RHIF, the Social Assistance Agency, the Agency for People with Disabilities and the bodies for medical expert examination of the capacity for work) shall be notified of the decisions of the TMEP and NMEP electronically, while complying with the conditions and procedures laid down in the Electronic Document and Electronic Trust Services Act, as well as the Electronic Government Act. The person recognised and the insurers shall be notified by a letter with acknowledgment of receipt or by electronic means under the terms and according to the procedure established by the Electronic Document and Electronic Trust Services Act and the Electronic Government Act.

Article 113

(1) The management, organisation and provision of resources for medical care in natural calamities, accidents and disasters shall be performed by the Minister of Health, the Chief State Health Inspector, the NCRRP director, the RHI directors, medical treatment and health care facilities.
(2) The head of NMEP may give instructions to review wrong or contradictory decisions of NMEP divisions within three months of the date of these decisions.
(3) The decisions of medical expert bodies, which have not been appealed against or all the remedies in connection with which have already been exhausted, shall be binding on all persons, bodies and organisations in this country.

Section V
Medical Care in Natural Calamities, Accidents and Disasters

Article 114

(1) (Amended, SG No. 98/2010, effective 1.01.2011) The management, organisation and provision of resources for medical care in natural calamities, accidents and disasters shall be performed by the Minister of Health, the Chief State Health Inspector, the NCRRP director, the RHI directors, medical treatment and health care facilities.

(2) (Amended, SG No. 102/2006, SG No. 102/2008, SG No. 93/2009, effective 25.12.2009) The authorities under Paragraph (1) shall carry out the medical care activities in natural calamities, accidents and disasters in close cooperation with the central and local government authorities, the Ministry of the Interior, non-governmental organisations and the Bulgarian Red Cross Society.

Article 115

(1) The Minister of Health shall develop plans for medical care in natural calamities, accidents and disasters, which shall be subject to approval by the Council of Ministers.

(2) On the basis of the action plans in natural calamities, accidents and disasters as approved by the Council of Ministers, the authorities under Article 114, Paragraph (1) shall:

1. create the necessary conditions for medical sorting, primary processing, treatment, rehabilitation and medical expert activities for the victims;
2. set up and train management bodies and medical teams;
3. ensure the protection of hospitalised patients and medical staff against external factors;
4. organise and carry out anti-epidemic and sanitary activities and control in the affected areas;
5. establish resource stock for medical activities;
6. organise the continuous training of medical specialists and the population in the field of medical care in natural calamities, accidents and disasters.

(3) (Amended, SG No. 15/2013, effective 1.01.2014) Healthcare in natural calamities, accidents and disasters shall be financed from the state budget.

Article 116

(1) (Amended and supplemented, SG No. 98/2010, effective 1.01.2011) A board for medical care in natural calamities, accidents and disasters shall be set up under the RHI director in order to provide medical care in cases of natural calamities, accidents and disasters. The RHI director shall be the board president.

(2) (Amended, SG No. 98/2010, effective 1.01.2011) The board under Paragraph (1) shall include one representative of the RHI; the directors of medical treatment facilities for in-patient health care and the centre for emergency medical care; and representatives of the regional administration and municipalities in the respective region.

(3) The board under Paragraph (1) shall adopt the regional action plans and the training programmes for medical teams operating in natural calamities, accidents and disasters.

Section VI
(New, SG No. 41/2009, effective 2.06.2009, repealed, SG No. 102/2018, effective 1.04.2019)
Controls of Medical Services

Article 116a

(New, SG No. 41/2009, effective 2.06.2009, amended, SG No. 101/2009, effective 1.01.2010, SG No. 15/2013, effective 1.01.2014, repealed, SG No. 102/2018, effective 1.04.2019).

Article 116b

(New, SG No. 41/2009, effective 2.06.2009, amended, SG No. 101/2009, effective 1.01.2010, SG No. 98/2010, effective 1.01.2011, SG No. 8/2011, effective 25.01.2011, SG No. 60/2011, effective 5.08.2011, amended, SG No. 102/2012, effective 21.12.2012, amended, SG No. 15/2013, effective 1.01.2014, repealed, SG No. 102/2018, effective 1.04.2019).

Article 116c

(New, SG No. 41/2009, effective 2.06.2009, amended, SG No. 101/2009, effective 1.01.2010, repealed, SG No. 102/2018, effective 1.04.2019).

Article 116d

(New, SG No. 41/2009, effective 2.06.2009, repealed, SG No. 102/2018, effective 1.04.2019).

Article 116e

(New, SG No. 41/2009, effective 2.06.2009, amended, SG No. 15/2013, effective 1.04.2014, repealed, SG No. 102/2018, effective 1.01.2019).

Article 116f

(New, SG No. 41/2009, effective 2.06.2009, amended, SG No. 101/2009, effective 1.04.2010, SG No. 38/2012, effective 1.07.2012, repealed, SG No. 102/2018, effective 1.01.2019).

Chapter Four
HEALTH PROTECTION OF SPECIFIC GROUPS OF THE POPULATION
Section I
Health Protection of Children

Article 117

Central and local government authorities, individuals and legal entities shall create conditions to ensure a healthy environment and normal physical and mental development of children.

Article 118

(1) Crèches and kitchens for children shall be set up to support families in raising children up to the age of three and to ensure their normal physical and mental development.
(2) Crèches shall be organisationally distinct structures, where medical and other specialists raise, educate and train children aged from three months to three years.
(3) Kitchens for children shall be organisationally distinct structures, where medical and other specialists prepare, keep and provide food for children aged up to three years.
(4) The requirements to the structure and activities of crèches and kitchens for children, as well as the norms for healthy nutrition of children aged up to three years shall be set out in regulations issued by the Minister of Health.

Article 119

(1) Crèches and kitchens for children may be set up by local governments, individuals and legal entities.
(2) (New, SG No. 110/2008, effective 1.01.2009, amended, SG No. 98/2010, effective 1.01.2011) Municipal crèches and kitchens may be set up, re-organised and closed by order of the mayor of the municipality, following a decision of the municipal council and the consent of the director of the respective RHI.
(3) (Renumbered from Paragraph 2, SG No. 110/2008, effective 1.01.2009) The support of children at municipal crèches and the operation of municipal kitchens for children shall be supported from the respective municipal budget.
(4) (Renumbered from Paragraph 3, SG No. 110/2008, effective 1.01.2009, amended, SG No. 17/2022, effective 1.04.2022) Parents and custodians shall pay fees for receiving food from municipal kitchens for children in amounts specified by the Municipal Council pursuant to the Local Taxes and Fees Act.
(5) (New, SG No. 66/2023, effective 1.01.2023) The state shall provide funds to parents to compensate for the costs directly related to upbringing, training and education of children aged from three months till 1 September of the year in which they attain three years, where said children:
1. have not been enrolled at municipal nurseries schools and nursery groups at state-owned and municipal kindergartens due to unavailability of places in the kindergartens in which the child has applied, and

2. an equally suitable place at a municipal nursery school or nursery group in a municipal kindergarten has not been offered by the municipality in which the child has their permanent address.
(6) (New, SG No. 66/2023, effective 1.01.2023) The monthly amount of the support per child referred to in paragraph 5 shall not exceed the average monthly amount of the maintenance allocation for a child enrolled in the system of pre-school education in municipal and state-owned kindergartens and schools for the relevant calendar year. The amount of said allocation shall be set out in a dedicated order of the Minister of Education and Science.
(7) (New, SG No. 66/2023, effective 1.01.2023) The support referred to in paragraph 5 shall be paid to parents in the amount of the actual monthly rearing and education costs and shall not exceed the amount referred to in paragraph 6. The funds shall be paid until the child is enrolled in a municipal nursery school or in a nursery group in a municipal kindergarten.
(8) (New, SG No. 66/2023, effective 1.01.2023) The terms and procedure regulating the provision and payment of the amounts referred to in paragraph 5 shall be set out in an ordinance of the Council of Ministers.

Article 120

(Amended, SG No. 95/2007, effective 1.01.2008)
(1) (Amended, SG No. 24/2019, effective 1.07.2020 - amended, SG No. 101/2019) Health offices in kindergartens and schools shall perform activities involving:
1. medical services for the provision of first medical aid to the children and pupils and medical services until the arrival of a specialized urgent medical aid team;
2. (new, SG No. 98/2016, effective 1.01.2017) support the process of monitoring and treatment of children with chronic diseases, prescribed by a doctor from the hospital that performs dispensary observation of the relevant chronic disease, specified in the ordinance under Article 30, Paragraph 3;
3. (renumbered from Item 2, SG No. 98/2016, effective 1.01.2017) promotion and prevention with regard to the children's and pupils' health;
4. (renumbered from Item 3, SG No. 98/2016, effective 1.01.2017, amended, SG No. 24/2019, effective 1.07.2020 - amended, SG No. 101/2019) organising and carrying out activities to prevent outbreaks and limit the spreading of infectious and parasitical diseases at the kindergartens and schools;
5. (renumbered from Item 4, SG No. 98/2016, effective 1.01.2017) participation in the preparation, conducting and control of the various forms of recreation, tourism and sports activities for the children and pupils;
6. (renumbered from Item 5, SG No. 98/2016, effective 1.01.2017, amended and supplemented, SG No. 58/2019) organisation and implementation of health education programs for the children and pupils, of special healthy diet programs, of programs to prevent deviations in diet habits, to prevent the use of narcotic and psychotropic substances, to prevent the use of tobacco and related products and alcoholic drinks, and to cultivate a sexual culture;
7. (renumbered from Item 6, SG No. 98/2016, effective 1.01.2017, amended, SG No. 24/2019, effective 1.07.2020 - amended, SG No. 101/2019) consultation on the weekly schedule of classes with the headmaster of the kindergarten and the school.
(2) (Amended, SG No. 98/2010, effective 14.12.2010) The activities under Paragraph (1) shall be carried out periodically and by university graduates of medicine with the vocational qualification of doctor and/or by other medical specialists with a bachelor's degree under Article 42, Paragraph (1), Item 1 of the Higher Education Act, in accordance with standards specified by the regulations under Article 26, Paragraph (2). The regulations shall also specify the powers, duties and responsibilities of the doctors and medical specialists working in the medical offices under Paragraph (1).
(3) (Amended, SG No. 41/2009, effective 2.06.2009, SG No. 98/2010, effective 14.12.2010, SG No. 24/2019, effective 1.07.2020 - amended, SG No. 101/2019) The medical practitioners or specialists, respectively, shall keep accounting and reporting records as per sample forms and

systematise the information from the doctor of dental medicine on the process of prevention and treatment regarding the dental status of the children and pupils at the kindergartens and schools.
(4) (Amended, SG No. 24/2019, effective 1.07.2020 - amended, SG No. 101/2019) The doctors and medical specialists under Paragraph (2) shall work under a contract with the mayor of the municipality on whose territory the kindergartens and schools are located, or with the person who has obtained a permit to open a private kindergarten, a private school or a private school.
(5) (Amended, SG No. 99/2009, effective 1.01.2010, SG No. 24/2019, effective 1.07.2020 - amended, SG No. 101/2019) The financing of the activities of the medical offices in the municipal and state schools and in the municipal and state kindergartens shall be carried out with funds from the municipal budgets as a state mandate. The activities of the medical offices opened in private kindergartens and schools shall be financed by their owners.
(6) (Amended, SG No. 41/2009, effective 2.06.2009, SG No. 98/2010, effective 1.01.2011) The activities performed by the medical offices shall be controlled by the relevant RHI.

Article 121

In the event of a detected disease or deviation in the development of a child, the specialists at health offices shall inform the parents, guardians or custodians and the general practitioner of the child.

Article 122

(1) The approved curriculum shall provide pupils with training in:
1. personal hygiene;
2. healthy nutrition;
3. healthy environment;
4. healthy life style;
5. prevention of infectious diseases;
6. (amended, SG No. 58/2019) health risks related to the use of tobacco and related products, alcohol and narcotic drugs;
7. sexual behaviour, prevention of sexually transmitted diseases and AIDS and prevention of undesired pregnancy;
8. first aid to victims.
(2) (Amended, SG No. 68/2013, effective 2.08.2013) The training of trainers in the issues under Paragraph (1) shall be organised by the Minister of Education and Science in accordance with training programmes consulted with the Minister of Health.
(3) School boards of trustees shall organise events to inform parents on children health issues.

Article 123

(1) (Amended, SG No. 24/2019, effective 1.07.2020 - amended, SG No. 101/2019) For the purposes of ensuring preventive medical and dental aid to children and pupils at crèches, kindergartens, schools and social and integrated health and social services for residential care for children, documents on examinations conducted shall be required or preventive medical and dental examinations shall be carried out.
(2) The terms and conditions for carrying out the preventive examinations under Paragraph (1) shall be set out in regulations issued by the Minister of Health.
(3) The activities under Paragraph (1) shall be financed by NHIF.

Article 124

(1) (Repealed, SG No. 24/2019, effective 31.12.2023 – amended, SG No. 110/2020, effective 31.12.2020, SG No. 8/2022, effective 1.01.2022, SG No. 104/2022, effective 1.01.2023).
(2) (Amended, SG No. 68/2013, effective 2.08.2013, SG No. 24/2019, effective 1.07.2020 - amended, SG No. 101/2019) The dental treatment beyond the scope of the National Framework Agreement of children at child institutions opened by the Ministry of Education and Science, the Ministry of Interior and the Ministry of Justice, as well as at social and integrated health and social services for residential care for children run by municipalities shall be paid by the respective institutions.

Article 125

An agreement with a medical treatment facility for out-patient care may be signed to provide additional or specialised medical services to children at the institutions under Article 123 (1).

Article 125a

(New, SG No. 41/2009, effective 2.06.2009)

(1) Medical professionals shall be bound to notify the Social Assistance Directorate with jurisdiction over their respective medical facility about each child born at that facility who is at risk of being abandoned including where the mother has no identification documents at the time of giving birth to the child concerned, in the case of single mothers, in the case of mothers of many or where the mother has serious or multiple diseases.

(2) Medical professionals working at medical treatment facilities or healthcare offices shall be bound to notify the authorities of the Ministry of Interior and the Social Assistance Directorate about each child admitted to their medical facility or who visited their healthcare office who has been a victim of abuse.

Section Ia
(New, SG No. 72/2015, repealed, SG No. 24/2019, effective 1.07.2020 - amended, SG No. 101/2019)
Integrated Health and Social Services

Article 125b

(New, SG No. 72/2015, repealed, SG No. 24/2019, effective 1.07.2020 - amended, SG No. 101/2019).

Article 125c

(New, SG No. 72/2015, repealed, SG No. 24/2019, effective 1.07.2020 - amended, SG No. 101/2019).

Article 125d

(New, SG No. 72/2015, repealed, SG No. 24/2019, effective 1.07.2020 - amended, SG No. 101/2019).

Section II
Reproductive Health

Article 126

(1) The government shall provide health protection of the reproductive health of citizens by means of:

1. promotion and consultations for protection of the reproductive health of children and persons in reproductive age;
2. ensuring access to specialised consultative aid on issues of reproductive health and family planning;
3. prevention and treatment of sterility;
4. specialised information, consultations, prevention and treatment of sexually transmitted diseases and AIDS;
5. prevention, treatment and dispensary monitoring of persons with malignant diseases of the reproductive system.

(2) Every person shall be entitled to information and freedom of choice with regard to his/her reproductive health.

Article 127

(1) For the purposes of ensuring risk-free maternity, every woman shall have access to health activities aimed at ensuring optimal health condition of the woman and the foetus from the beginning of the pregnancy to the 42nd day of the child.

(2) The health activities under Paragraph (1) shall include:

1. promotion aimed at protecting the health of the woman and the foetus;

2. prevention of the threat of abortion and premature childbirth;
3. training in the feeding and care of infants;
4. active medical monitoring of pregnancy on the basis of the dispensary principle at medical treatment facilities for primary and specialised out-patient health care;
5. pre-natal diagnostics and prevention of genetic and other diseases under terms and conditions set out in regulations issued by the Minister of Health;
6. ensuring optimal living environment for mothers and infants;
7. dispensary monitoring and healthcare for mothers and infants;
8. free access of pregnant women or mothers of infants to medical treatment facilities for specialised out-patient health care;
9. free access of pregnant women to medical treatment facilities for specialised out-patient and in-patient health care in conditions threatening the pregnancy;
10. the freedom of choice of an in-patient medical treatment facility for childbirth by pregnant women.

Article 128

(1) The terms and conditions for performing artificial abortions and the foetus viability criteria shall be set out in regulations issued by the Minister of Health.
(2) The regulations under Paragraph (1) shall specify also the obligations of medical specialists in the case of suspected abortions carried out beyond the terms and conditions set out in this Act.
(3) The lasting removal of the ability to reproduce shall be carried out under terms and conditions set out in regulations issued by the Minister of Health.

Section III
Assisted Reproduction

Article 129

Assisted reproduction shall be applied, where the condition of the man or the woman prevents the natural performance of their reproductive functions.

Article 130

(1) Assisted reproduction shall be carried out upon the informed consent given in writing by the persons willing to have progeny.
(2) Assisted reproduction shall be carried out after the conduct of medical tests to guarantee the health of the progeny.
(3) (Amended, SG No. 71/2006, effective 1.01.2007) Assisted reproduction shall be carried out in accordance with the medical standards approved by an ordinance of the Minister of Health.
(4) (New, SG No. 71/2006, effective 1.01.2007) Assisted reproduction shall include the activities related to:
1. the application of medical methods for fertilization of an egg located inside or outside the body of the woman;
2. (supplemented, SG No. 36/2009) the removal, expert examination, processing, labelling, procurement, transportation and preservation of eggs, sperm or zygotes;
3. the removal of an egg from one woman and the implantation thereof into the body of the same woman;
4. the removal of an egg from one woman and the implantation thereof into the body of another woman.
(5) (New, SG No. 71/2006, effective 1.01.2007) Removal of eggs from a donor in the cases referred to in Item 4 of Paragraph (4) may be effected providing the following conditions have been met:
1. (amended, SG No. 67/2020) the donor is of full age, has not been placed under interdiction and meets the criteria set out in the medical standard under paragraph 3, which guarantee the safety of the donor and the quality of the egg;
2. a written agreement from the donor has been received, notarized by a notary in whose judicial district the medical facility which will implement the extraction is located;

3. the donor has been informed in understandable language as regards the risks that person is undertaking;
4. the physical and mental health of the donor has been established with a memorandum signed by the members of a commission appointed by the director of the medical facility implementing the extraction, which shall consist of at least three doctors who do not participate in the team on the extraction.
(6) (New, SG No. 71/2006, effective 1.01.2007, amended, SG No. 36/2009, SG No. 102/2018, effective 1.04.2019) Medical treatment facilities shall be obligated to prepare an annual report on the activities implemented pursuant to Paragraph (4) in a form established by the ordinance referred to in Article 131 (7) and shall submit it to the Medical Supervision Executive Agency.
(7) (New, SG No. 71/2006, effective 1.01.2007) Offering pecuniary benefit to a donor of eggs or sperm, as well as acceptance of pecuniary benefit by the donor shall be prohibited.

Article 131

(Amended, SG No. 71/2006, effective 1.01.2007, supplemented, SG No. 36/2009, SG No. 41/2009, effective 2.06.2009, SG No. 77/2018, effective 1.01.2019, amended, SG No. 102/2018, effective 1.04.2019) (1) Assisted reproduction, as well as the provision, use and storage of human eggs, sperm and zygotes shall be implemented by:
1. medical treatment facilities for in-patient care that have obtained authorisations in accordance with the procedure established by Article 48(1) of the Medical-Treatment Facilities Act and said authorisation expressly contains said activities;
2. medical treatment facilities for out-patient care registered in accordance with the procedure established by Article 40 of the Medical-Treatment Facilities Act whose registration certificate contains said activities;
3. medical treatment facilities under the Council of Ministers, the Ministry of Defence, the Ministry of Interior and the Ministry of Transport, Information Technology and Communications after obtaining a certificate from the Ministry of Health, on a motion by the Executive Director of the Medical Surveillance Executive Agency, to the effect that the medical treatment facility satisfies the requirements of the medical standard for assisted reproduction, which explicitly indicates said activities.
(2) On a motion by the Executive Director of the Medical Supervision Executive Agency, the Minister of Health can suspend with an order activities related to assisted reproduction for a period of 6 months if the medical treatment facility does not comply with the requirements of the medical standard for assisted reproduction.
(3) In the event that the medical facility still does not comply with the requirements of the medical standard on assisted reproduction after the period provided for in Paragraph (2) has expired, on a motion by the Executive Director of the Medical Supervision Executive Agency the Minister of Health can with an order:
1. withdraw the authorisation for carrying out medical activities in its part concerning assisted reproduction and provision, use and storage of human eggs, sperm and zygotes: in respect of the medical treatment facilities referred to in Item 1 of Paragraph (1);
2. delete from the registration of the medical treatment facilities referred to in Item 2 of Paragraph (1) the activities related to assisted reproduction and provision, use and storage of human eggs, sperm and zygotes;
3. withdraw the certificate of the medical treatment facilities referred to in Item 3 of Paragraph (1) and notify the relevant first-level budget authoriser to which the director of the medical treatment facility is a second-level budget authoriser.
(4) The Minister of Health can, by an order, also impose the measures specified in Paragraph (3) where the medical treatment facility carries out activities in violation of this Act and the instruments of secondary legislation on its implementation or carries out assisted reproduction activities not covered by the authorisation or certificate, as the case may be.

(5) The orders referred to in Paragraphs (2), (3) and (4) shall be subject to appeal before the competent administrative court according to the procedure established by the Code of Administrative Procedure.
(6) Medical treatment facilities shall carry out all medical activities related to the testing, preparation and continuous monitoring of the persons subjected to assisted reproduction, and shall control the condition of their health until childbirth.
(7) The terms and conditions for removal, implantation, expert examination, processing, labelling and preservation of eggs, sperm or zygotes for the needs of assisted reproduction, as well as of the materials and products coming in contact therewith and their tracing from the donor to the recipient, shall be laid down in an ordinance issued by the Minister of Health and shall be controlled by Executive Agency "Medical Audit".

Article 131a

(New, SG No. 36/2009)
(1) (Amended, SG No. 102/2018, effective 1.04.2019) In execution of their competences provided for in Article 131 (7), the Executive Agency "Medical Audit" shall:
1. register, store and analyse the information on the donor's details, the recipient's health status, serious adverse reactions and serious incidents related to assisted reproduction;
2. study and analyse medical, legal, ethical, religious, economic and social ramifications of assisted reproduction;
3. control the activities for quality and safety assurance during assisted reproduction;
4. every three years prepare a report to the European Commission on the activities to promote and encourage voluntary and free-of-charge donation of eggs, sperm and zygotes;
5. every three years submit a report to the European Commission on the activities to ensure the quality and safety during expert examination, removal, treatment, labelling, preservation, procurement and implantation of eggs, sperm and zygotes, the controls and inspections carried out.
(2) (Amended, SG No. 102/2018, effective 1.04.2019) The Executive Agency "Medical Audit" shall take part in the development of national strategies and programmes, international projects, analyses of and forecasts regarding assisted reproduction.
(3) (Amended, SG No. 102/2018, effective 1.04.2019) The Medical Supervision Executive Agency shall create and maintain:
1. a public register;
2. an official register.
(4) The circumstances and the data to be entered into the registers referred to in Paragraph (1), the procedure for entering and using the information shall be laid down in an ordinance of the Minister of Health.
(5) The data recorded into the public register shall be accessible to all people under the terms and the procedure laid down in the Access to Public Information Act.
(6) The data recorded into the official register shall be kept for a period of 30 years.
(7) Health information recorded into the official register shall be provided in accordance with the procedure referred to in Article 28 of the Health Act.

Article 132

(1) (Amended, SG No. 71/2006, effective 1.01.2007) The medical treatment facilities referred to in Article 131 (1) shall create and maintain a register that shall contain:
1. data about each case of removal, expert examination, processing, labelling and preservation of eggs, sperm or zygotes;
2. the forename, patronymic and family name, personal identity number, permanent address and unique identification number of the persons who have donated eggs or sperm;
3. the unique identification number of eggs, sperm or zygotes removed, related to the number pursuant to Item 2;

4. the forename, patronymic and family name, the personal identity number, permanent address and unique identification number of the woman to whom eggs, sperm or zygotes have been implanted, related to the number pursuant to Item 3.
(2) Any disclosure of data which may lead to identification of donors or recipients of eggs or sperm, where the donor is a person other than the man or woman willing to have progeny, shall be prohibited, unless ruled otherwise by law.
(3) The data in the register under Paragraph (1) shall be deemed to be official information and shall be kept for 30 years.
(4) (Amended, SG No. 71/2006, effective 1.01.2007, SG No. 36/2009, SG No. 102/2018, effective 1.04.2019) The terms and conditions for the registration, processing, storage and provision of the information in the register under Paragraph (1) shall be set out in the ordinance under Article 131 (7).

Article 132a

(New, SG No. 71/2006, effective 1.01.2007)
(1) (Amended, SG No. 102/2018, effective 1.04.2019) The medical treatment facilities referred to in Article 131 (1) shall be obligated to notify the Executive Agency "Medical Audit" within seven days of establishment of all serious adverse reactions or serious incidents where these are the result of removal, expert examination, processing, labelling and preservation of eggs, sperm and or zygotes and are related to the quality and safety thereof.
(2) The medical treatment facilities pursuant to Article 131 (1) shall be obligated to create and apply a system for immediate retention, recall or destruction of all eggs, sperm or zygotes which may lead to a serious adverse reaction or a serious incident.
(3) The conditions and procedure for notification, registration, reporting and relay of information about the serious adverse reactions and the serious incidents, as well as for retention, recall and destruction of eggs, sperm or zygotes shall be determined by an ordinance of the Minister of Health.

Article 132b

(New, SG No. 71/2006, effective 1.01.2007)
(1) Medical treatment facilities shall be obligated to label the eggs, sperm and zygotes removed.
(2) (Amended, SG No. 36/2009, SG No. 102/2018, effective 1.04.2019) The medical treatment facilities referred to in Article 131 (1) shall be obligated to create conditions for tracing the eggs, sperm and zygotes, as well as the products and materials that come into contact therewith and are related to their quality and safety, under conditions and by a procedure established by the ordinance referred to in Article 131 (7).

Article 133

No artificial fertilization of an egg with sperm of a donor who is a lineal or collateral consanguineal relative up to four times removed from the woman to whom the egg belongs shall be allowed. These circumstances shall be certified with a statement in writing by the persons willing to have progeny.

Article 134

(1) (New, SG No. 71/2006, effective 1.01.2007, amended, SG No. 36/2009) Export and import of eggs, sperm and zygotes shall be effected under conditions and by the procedure of Articles 37 and 38 of the Organ, Tissue and Cell Transplantation Act.
(2) (Previous text of Article 134, SG No. 71/2006, effective 1.01.2007) Eggs, sperm and fertilized eggs which have not been used for creating progeny may be provided to research, educational and medical treatment facilities in this country and abroad for medical, research and educational purposes upon receipt of the informed consent in writing of the donor or, in the case of fertilized eggs, by the two donors under terms and conditions set out in an ordinance issued by the Minister of Health.

Article 135

(1) Assisted reproduction techniques for selection of the gender of the progeny shall be prohibited, unless gender-related hereditary diseases have to be prevented.

(2) Assisted reproduction techniques for transmission of the genetic information of one individual only shall be prohibited.
(3) The reproductive cloning of people shall be prohibited, including that for the purposes of donating organs, tissues and cells.
(4) Any intervention aimed at modifying the human genome may be undertaken only for preventive or therapeutic purposes and not for the purposes of introducing the modification into the genome of the progeny.

Article 136

Any form of genome-based discrimination shall be prohibited.

Section IV
Genetic Health and Genetic Tests

Article 137

The protection of genetic health shall be ensured through health activities aimed at:
1. preventive and diagnostic tests to prove and classify genetic diseases;
2. dispensary registration of persons with higher risk of occurrence and development of genetic diseases;
3. treatment of hereditary diseases, innate anomalies and predispositions;
4. identification of hereditary signs and identification of a parent;
5. preservation of genetic information.

Article 138

Preventive genetic tests shall be conducted for the following purposes;
1. to identify the risk of occurrence of a genetic diseases in the progeny;
2. to identify clinically healthy carriers of genetic deviations;
3. to diagnose hereditary and other diseases before and during pregnancy and after birth.

Article 139

(1) Genetic tests before childbirth shall be conducted in cases of proven risk of transmission of a genetic disease to the progeny.
(2) The tests under Paragraph (1) shall be carried out under medical control and shall include:
1. proving genetic deviations in cases of clinically healthy and ill patients;
2. establishing predisposition to a genetic disease;
3. establishing genetic deviations as a result of the life style or the external environment;
4. proving genetic diseases upon their clinical manifestation.

Article 140

Special studies shall be conducted to establish the type and frequency of genetic deviations and to identify the genetic stock through national health programmes.

Article 141

(1) Genetic tests and the taking of biological material for genetic tests for medical or research purposes shall be carried out only upon receipt of the informed consent of the tested persons given in writing.
(2) Genetic tests of children, persons with mental disorders and persons who have been put under legal incapacity shall be carried out also at the permission of the commission for medical ethics at the respective medical facility.
(3) The results of genetic tests and screening may not be used for discrimination against the tested persons.
(4) The information about the human genome of persons shall constitute personal data and may not be disclosed to employers, health insurance organisations and insurance companies.

Article 142

(1) Genetic tests for medical or research purposes shall be carried out by accredited:
1. genetic laboratories at medical treatment facilities for in-patient health care;

2. genetic laboratories at medical treatment facilities for out-patient health care;
3. independent laboratories.
(2) The Minister of Health shall issue an order on the National Genetic Laboratory.
(3) The laboratory under Paragraph (2) shall provide methodological guidance and supervision of the activities of genetic laboratories.
(4) The National Genetic Laboratory shall establish and maintain a national genetic register.
(5) The terms and conditions for the operation of the National Genetic Laboratory and the register under Paragraph (4) shall be set out in an ordinance issued by the Minister of Health.

Article 143

(1) The medical treatment facilities under Article 142 (1) shall inform the National Genetic Laboratory on a monthly basis of the genetic tests performed and the results thereof.
(2) The medical treatment facilities under Paragraph (1) shall establish and maintain an administrative register of the tests they have performed.
(3) The structure of the laboratories under Paragraph (1) shall be set out in an ordinance issued by the Minister of Health, while their activities and the procedures for registration, storage, processing and access to the information in the register shall be set out in the ordinance under Article 142, Paragraph (5).

Article 144

(1) The genetic laboratories at medical treatment facilities may set up DNA banks for removal and preservation genetic material for research and medical purposes.
(2) The medical treatment facilities under Paragraph (1) shall register their DNA banks with the Ministry of Health within seven days under terms and conditions set out in the ordinance under Article 142 (5).

Article 144a

(New, SG No. 1/2014, effective 3.01.2014)
(1) A national register of rare disease patients shall be created for the purposes of establishing the type and frequency of rare diseases and for the purposes of planning and providing rare disease-related preventive, diagnostic and therapeutic activities.
(2) The terms and procedures for recording rare diseases shall be set out in regulations issued by the Minister of Health.
(3) The regulations under paragraph 2 shall specify also the conditions and criteria for medical treatment facilities willing to join the European Reference Networks, and the procedures for the establishment, designation and functioning of rare disease expert centres and reference networks.

Chapter Five
MENTAL HEALTH
Section I
Protection of Mental Health

Article 145

(1) Central and local government authorities and non-governmental organisations shall organise activities for the protection of mental health related to:
1. the provision of accessible and high-quality medical aid, care and support to persons with mental disorders, which they need for their life in the family and the community;
2. (amended, SG No. 24/2019, effective 1.07.2020 - amended, SG No. 101/2019) the protection of the mental health in risk groups: children, students, aged people, persons using social and integrated health and social services for residential care, servicemen, arrested persons and prisoners;
3. the active prevention of mental disorders;
4. the support to public initiatives in the field of mental healthcare;
5. the specialised continued training of persons involved in the protection of mental health;

6. the implementation of mental health strengthening and protection training programmes for the persons who train and perform medical activities, social adaptation, organisation and management, and protection of the public order;
7. applied research oriented to the strengthening of mental health;
8. public awareness of mental health issues.
(2) Local governments shall create conditions for psycho-social rehabilitation and financial and material support, including housing, to persons with mental disorders.

Article 146

(1) Persons with mental disorders in need of special healthcare are as follows:
1. mental patients with established serious mental dysfunction (psychosis or severe disorder of the personality) or pronounced long-term mental damage as a result of a mental disease;
2. persons with moderate, severe or deep mental handicap or vascular and senile dementia;
3. persons with other mental dysfunctions, learning handicaps and adaptation difficulties, which require medical aid, care and support to live fully in the family and the community.
(2) Any person with mental disorders shall receive treatment and care under conditions equal to those offered to other patients.

Article 147

(1) No person may be subject to medical activities for the establishment or treatment of a mental disorder, unless prescribed by law.
(2) The assessment of an existing mental disorder may not be based on family, professional or other conflicts or information of a mental disorder in the past.

Article 147a

(New, SG No. 41/2009, effective 2.06.2009)
(1) The Ministry of Health shall establish and maintain a National Official Register of People with Mental Disorders. The terms and conditions for keeping the register and using the data contained therein shall be laid down in an ordinance to be issued by the Minister of Health.
(2) The terms and condition for official exchange of information on persons with mental disorders who apply for jobs involving work with hazardous materials shall be laid down in an ordinance to be issued by the Minister of Health after consultation with the Minister of Interior in compliance with the requirements for confidentiality.

Article 148

The following fundamental principles shall apply to the treatment of persons with mental disorders:
1. minimization of the restriction of personal freedom and respect for the patient's rights;
2. reduction of the institutional dependence of persons with mental disorders on long-term hospital treatment provided that this does not contravene the established medical standards;
3. development of a broad network of specialised facilities for out-patient psychiatric care and priority of the care in the family and the community;
4. integration and equality of psychiatric care among the other branches of medicine;
5. observance of humanitarian principles and norms in the therapeutic process and social adaptation;
6. encouragement of self-assistance and mutual assistance and active public and professional support to persons with mental disorders;
7. specialised training, vocational training and re-training of persons with mental disorders with a view to their social adaptation;
8. participation of humanitarian non-governmental organisations in the process of treatment and social adaptation.

Article 149

(1) (Amended, SG No. 59/2010, effective 31.07.2010) The treatment of persons with mental disorders shall be carried out by medical treatment facilities for primary or specialised out-patient health care, medical treatment facilities for in-patient mental health care, mental health centres, specialised wards in multi-profile hospitals and medical and social care homes.

(2) The medical activities related to the treatment of persons with mental disorders shall include diagnostic tests, pharmaceutical and instrumental methods of treatment and psychotherapy. The terms and conditions for their performance shall be set out in an ordinance issued by the Minister of Health.
(3) The use of surgical methods for change of the morphology of the central nerve system with a view to attaining specific psychic characteristics shall be prohibited.

Article 150

(1) Measures for temporary physical constraint may be applied to patients with established mental dysfunction in a condition that represents a direct and immediate threat to their own life and health or the life and health of other people.
(2) The measures under Paragraph (1) shall be applied only as a precondition for the treatment and shall not replace the active treatment.
(3) The undertaking of temporary physical constraint measures shall be performed at the instructions of a medical doctor, specifying the type of measure and its duration. This duration may not be longer than six hours.
(4) The measures under Paragraph (1) shall be carried out by staff specially trained for this purpose.
(5) The type of the physical constraint measures undertaken, the reasons for their undertaking, their duration and the name of the medical doctor who has given the instructions shall be entered into a special journal of the medical facility and in the history of the case.
(6) The person under physical constraint measures shall be continuously monitored by a medical doctor or a nurse.
(7) The type and manner of applying physical constraint measures shall be set out in the established medical standards.
(8) The terms and conditions for the application of physical constraint measures shall be set out in an ordinance issued by the Minister of Health together with the Minister of Justice.

Article 151

(1) The labour therapy of persons with mental disorders shall be incorporated in psycho-social rehabilitation programmes.
(2) All forms of exploitation and coercion shall be ruled out in the implementation of labour therapy.
(3) The activities related to the organisation, working conditions and remuneration of work shall be set out in an ordinance issued by the Minister of Health in consultation with the Minister of Labour and Social Policy and the Minister of Finance.

Article 152

(1) (Amended, SG No. 24/2019, effective 1.07.2020 - amended, SG No. 101/2019) Social and integrated health and social services for residential care for more than 20 people with mental disorders shall establish health offices with a medical doctor, a paramedic or a nurse.
(2) Health offices shall perform activities involving:
1. continuous medical monitoring;
2. the provision of first medical aid;
3. control of the hygiene of persons;
4. operational control over the observance of sanitary requirements;
5. the preparation and keeping of medical records of each person.

Article 153

(1) Urgent psychiatric aid is a set of medical rules and activities applied to persons with apparent signs of mental disorders, where their behaviour of condition represents a direct and immediate threat to their own life and health or the life and health of other people.
(2) (Amended, SG No. 59/2010, effective 31.07.2010) Urgent psychiatric aid shall be provided by mental health centres, medical treatment facilities for mental hospital aid, psychiatric wards or clinics at multi-profile hospitals and urgent medical aid centres.

(3) Urgent psychiatric aid shall be provided in accordance with the established medical standards.

Article 154

(1) Where the condition of a person under Article 146, Items 1 and 2 of Paragraph (1), warrants continuation of the treatment after the urgent condition is put under control, the head of the medical facility shall make a decision to have the person temporarily accommodated for treatment for not more than 24 hours, informing the patient's relatives thereof forthwith.
(2) By way of exception, the term under Paragraph (1) may be renewed by up to 48 hours with the permission of the district judge.
(3) If a decision to conduct mandatory treatment is needed, the head of the medical facility shall immediately petition the court and serve also an opinion on the mental condition of the person drawn up by a psychiatrist.

Section II
Mandatory Accommodation and Treatment (*)

(*) *Editor's note.* With respect to the adoption of compulsory medical measures, see JUDGMENT OF THE COURT (Third Chamber) of 19 September 2019 IN CASE C-467/18 (Lom Regional Prosecutor's Office against EP)

Article 155

Subject to mandatory accommodation and treatment shall be the persons under Article 146, Items 1 and 2 of Paragraph (1), who, due to their disease, may commit an offence threatening their relatives, the people around them or the community or seriously threatening their health.

Article 156

(1) The mandatory accommodation and treatment of the persons under Article 155 shall be implemented upon a decision of the district court at the current address of the person or, in the cases under Article 154, of the district court at the location of the medical facility.
(2) (Amended, SG No. 59/2010, effective 31.07.2010) The mandatory treatment aid shall be provided by medical treatment facilities for mental hospital aid and mental health centres, psychiatric wards or clinics at multi-profile hospitals and medical treatment facilities for specialised psychiatric out-patient care.

Article 157

The mandatory accommodation and treatment may be demanded by the public prosecutor and, in the cases under Article 154, (3), also by the head of the medical facility.

Article 158

(1) The court shall send copies of the request for mandatory accommodation and treatment of the person whose case will be heard. The person may raise objections and produce evidence within seven days.
(2) The court shall hear the case in a public session with the participation of the person within 14 days of the date of the request.
(3) Where the district judge has given the permission under Article 154 (2), the court shall hear the case immediately and the provisions of Paragraph (1) shall not apply. The copies shall be delivered during the court session and the head of the medical facility shall make arrangements for the person to appear.
(4) The participation of a psychiatrist, legal defence and a public prosecutor shall be mandatory.
(5) (Supplemented, SG No. 110/2020, effective 30.06.2021; declared unconstitutional by the Constitutional Court of the Republic of Bulgaria in respect of the third sentence - SG No. 94/2022)

The person whose case is heard shall be questioned in person and, if necessary, brought to the court room. Where the health condition of the person prevents him/her from appearing in the court session, the court shall acquire immediate impressions of the person's condition. In such cases, as well as in a declared state of emergency, martial law, disaster, epidemic, emergency epidemic situation or other force majeure circumstances, the person whose case is heard, as well as the expert appointed to give an expert opinion, may participate in the case by videoconference too, and their identity shall be certified by the director of the medical treatment facility or by a person authorised by them.

Article 159

(1) The court shall issue instructions on the preparation of a forensic expert medical opinion and report, having established the existence of any of the circumstances under Article 155 and having heard a psychiatrist as to the likelihood of a mental disorder of the person. The court shall rule on the form of the forensic expert medical activities – out-patient or in-patient.

(2) The court shall designate the medical facility and the expert to perform the forensic expert medical activities and the time limits for their performance, which may not be longer than 14 days, and schedule the next court session on the case within 48 hours of the completion of the forensic expert medical opinion and report.

(3) Where the time limits for the forensic expert medical opinion and report prove insufficient, by way of exception, the court may rule in a public session to renew it once by up to ten days. In such cases, the court shall reschedule the court session scheduled under Paragraph (2).

(4) Where the court establishes that the circumstances under Article 155 do not exist or it is not established that the person has a mental disorder after the hearing of the psychiatrist, the proceedings shall be dropped.

Article 160

(1) (Supplemented, SG No. 45/2011, effective 14.06.2011) The forensic expert medical opinion and report under Article 159 (1) shall be performed under terms and conditions set out in an ordinance issued by the Minister of Health and the Minister of Justice.

(2) During the conduct of the forensic expert medical activities, no treatment shall be applied, except for urgent conditions and upon the informed consent of the person.

(3) The expert shall give the forensic expert medical opinion and report, as well as an opinion on the capability of the person of giving an informed consent with the treatment, a proposal for the treatment of the respective disease, and a recommendation on the medical treatment facilities to perform the treatment.

Article 161

(1) The court ruling on the dropping of proceedings or the appointment of forensic expert medical activities shall be subject to private appeal or protest within three days. The appeal shall stay the forensic expert medical activities, unless the court rules otherwise.

(2) The district court shall pass judgement on the appeals in an open hearing. Failure of the accused party to appear shall not be an obstacle to the examination of the case.

Article 162

(1) Having heard the person with regard to the forensic expert medical opinion and report, the court shall rule on the case on the basis of the evidence collected.

(2) In its judgement, the court shall rule on the need for mandatory accommodation and specify the medical facility, as well as the existence or non-existence of capability of the person to give informed consent. The court shall establish the duration of the accommodation and treatment, as well as the form of treatment – out-patient or in-patient.

(3) Where non-existence of capability of the person is assumed, the court shall rule on mandatory treatment and appoint a person from among the relatives of the patient to give the informed consent

with the treatment. In the case of conflict of interests or lack of relatives, the court shall appoint a representative of the municipal healthcare service or a person designated by the mayor of the municipality to give the informed consent with the treatment of the person.

Article 163

(1) The court judgement shall be subject to appeal by the parties concerned within seven days of its ruling. The regional court shall rule within seven days and its judgement shall not be subject to appeal.
(2) The appeal against a judgement on mandatory accommodation and treatment shall stay its enforcement, unless the first instance or appellate court rules otherwise.

Article 164

(1) The mandatory treatment shall be terminated upon the expiration of the time limit for which it was adjudicated or at a decision of the district court at the location of the medical facility.
(2) The district court at the location of the medical facility shall pass a decision, of its own motion, as to whether to terminate the mandatory accommodation and treatment or to continue the mandatory accommodation and treatment pursuant to Articles 158, 159, 160 and 161. Such decisions shall be issued on a quarterly basis and in accordance with the relevant forensic expert medical opinion and report.
(3) Where the prerequisites for mandatory accommodation and treatment are eliminated prior to the expiration of the time limits, the court may terminate the mandatory accommodation and treatment at the request of the person, the public prosecutor or the head of the medical facility.

Article 165

(1) The provisions of the Criminal Procedure Code shall apply, unless this Section provides for some special rules.
(2) The enforceable judgement on mandatory accommodation and treatment and the court ruling on forensic expert medical activities shall be implemented by the respective medical treatment facilities with the assistance of the authorities of the Ministry of Interior, if needed.

Chapter Six
NON-CONVENTIONAL METHODS FOR FAVOURABLE IMPACT ON INDIVIDUAL HEALTH

Article 166

(1) The Minister of Health shall control the application of non-conventional methods for favourable impact on individual health, including:
1. the use of non-pharmaceutical products of organic origin;
2. the use of non-pharmaceutical products of mineral origin;
3. the use of non-conventional physical methods;
4. homeopathy;
5. acupuncture and acupressure;
6. iris, pulse and auricular methods of testing;
7. dietetics and curative hunger.
(2) The use of non-conventional methods for favourable impact on individual health other than those under Paragraph (1) shall be prohibited.
(3) The Minister of Health shall issue an ordinance to set out the requirements to persons applying non-conventional methods for favourable impact on individual health.

Article 167

(1) (Supplemented, SG No. 59/2006) Eligible to practice non-convention methods under Article 166 (1), except for homeopathy, shall be Bulgarian citizens and citizens of a European Union member-state, the other states from the European economic space and Switzerland, who are mentally healthy, who have not been convicted for felony and who meet any of the following conditions:
1. they are holders of a master’s degree in the professional areas of medicine, dental medicine or pharmacology;

2. (amended, SG No. 85/2005) they are holders of a specialist's or bachelor's degree in the professional area of health care;
3. (amended, SG No. 74/2009, SG No. 68/2013, effective 2.08.2013) they are holders of secondary education diploma and a certificate of completed training of at least four semesters at a higher medical school under terms and conditions set out in an ordinance issued by the Minister of Health and the Minister of Education and Science.
(2) (Supplemented, SG No. 59/2006) Eligible to practice homeopathy shall be Bulgarian citizens and citizens of a European Union member-state, the other states from the European economic space and Switzerland, who are holders of a master's degree in the professional areas of medicine or dental medicine.

Article 168

Persons practising non-conventional methods shall:
1. act in good faith;
2. prevent any harm to the health of the persons seeking their assistance;
3. explain to the persons seeking their assistance in detail and in a comprehensible language what non-conventional method they will apply and what results they expect;
4. obtain the explicit consent of the persons seeking their assistance on the application of the respective method given in writing;
5. not mislead the persons seeking their assistance, including the opportunities for achieving an impact on their health condition through the non-conventional method practised.

Article 169

All forms of advertising non-conventional methods, including their association with preventive, diagnostic, therapeutic and rehabilitation activities shall be prohibited.

Article 170

(1) (Amended, SG No. 98/2010, effective 1.01.2011) Persons practising non-conventional methods shall register at the RHI in the region where they operate by submitting an application accompanied by documents which certify that the requirements under Article 167 have been complied with.
(2) The application shall give an exhaustive description of the non-conventional methods and means that the person will apply.
(3) (Amended, SG No. 98/2010, effective 1.01.2011) Where the documentation is incomplete or the registration requirements are not met, the RHI director shall advise the person thereof within 15 days and give a ten-day time limit for removal of inconsistencies.
(4) (Amended, SG No. 98/2010, effective 1.01.2011) Within 15 days of the date of the application or the removal of inconsistencies, the RHI director shall issue a registration certificate, specifying the types of non-convention methods to be applied by the person or refuse to issue such a certificate with the reasons thereof.
(5) (Amended, SG No. 98/2010, effective 1.01.2011) The RHI director may refuse to register the applicant, where the non-conventional method described in the application contravenes the statutory requirements.
(6) The refusal of registration may be appealed against under the procedure of the Administrative Procedure Code.
(7) A registration fee shall be paid in amounts set by the Council of Ministers.

Article 171

(1) (Amended, SG No. 98/2010, effective 1.01.2011) The regional health inspection shall establish and maintain a register of persons practising non-conventional methods. The register shall be public and shall contain:
1. the serial number;
2. the date of the non-conventional practice registration certificate;
3. details of the person practising non-conventional methods - name, personal identification number and permanent address;

4. a description of the non-conventional method practised by the person;
5. the registration number of the visitors' journal under Article 173;
6. the date of deletion of the registration and the reasons thereof;
7. any changes of the circumstances set out in items 1 to 6;
8. any comments on the registered circumstances.
(2) (Amended, SG No. 98/2010, effective 1.01.2011) Registered persons shall notify the respective RHI of any changes in the non-conventional practice registration, within seven days of the date when the change occurred.

Article 171a

(New, SG No. 98/2010, effective 1.07.2011, amended, SG No. 85/2017)
The application under Article 170(1) and the notification under Article 171(2) may be submitted electronically, signed with an advanced electronic signature, advanced electronic signature based on a qualified certificate for electronic signatures, or qualified electronic signature pursuant to the requirements of Regulation (EU) No. 910/2014 and of the Electronic Document and Electronic Trust Services Act, as well as the Electronic Government Act.

Article 172

(1) The registration shall be deleted in any of the following cases:
1. at the request of the person who has registered the non-conventional practice;
2. upon the death of the registered person or putting him/her under legal incapacity;
3. in the case of presenting untrue statements in the documents under Article 170 (1);
4. in the case of activities in violation of the registration;
5. upon the establishment of unfavourable effects on human health as a result of the non-convention methods applied by the registered person.
(2) (Amended, SG No. 98/2010, effective 1.01.2011) The deregistration shall be conducted by order of the RHI director.
(3) The orders under Paragraph (1), items 3, 4 and 5 shall be subject to appeal pursuant to the Code of Administrative Procedure.
(4) The appeal against an order shall not stay its enforcement.

Article 173

(1) Persons practising non-conventional methods shall enter the details of each person seeking their assistance in the visitors' journal as follows:
1. the date of each visit;
2. the number of each visit;
3. the full name, personal identification number and permanent address;
4. all complaints reported during the visit;
5. the non-conventional activities performed.
(2) (Amended, SG No. 98/2010, effective 1.01.2011) The visitors' journal shall be bound, sealed and registered by the RHI which has made the registration.
(3) Persons practising non-conventional methods shall keep the visitors' journal for ten years after its finalization and submit it to controlling authorities upon request.

Chapter Seven
MEDICAL EDUCATION. MEDICAL PROFESSION. MEDICAL SCIENTIFIC RESEARCH ON PEOPLE. MEDICAL SCIENCE
Section I
Medical Education

Article 174

(1) Medical education shall provide and guarantee the volume and quality of training of the medical and non-medical specialists working in the national healthcare system.
(2) The fundamental principles of medical education shall be as follows:

1. continuous and high-quality teaching and mastering of a guaranteed volume of theoretical knowledge and practical skills;
2. stage-by-stage conduct and continuous nature of the training;
3. freedom of choice of a specialty.

Article 175

(1) (Supplemented, SG No. 17/2016, effective 1.03.2016) Education and training for the acquisition of a Master's degree in the occupational areas "Medicine", "Dental Medicine", "Pharmacy" and "Public Health" shall be available from the departments of tertiary educational institutions accredited pursuant to the Higher Education Act. Education and training on the basis of programmes for the academic disciplines included in the single educational requirements referred to in Article 177 may also be provided the registered branches of higher education institutions in countries other than Bulgaria.
(2) (Amended, SG No. 85/2005, effective 1.09.2006, supplemented, SG No. 41/2009, effective 2.06.2009, amended, SG No. 98/2010, effective 1.01.2011) The training for and acquisition of a Bachelor's degree referred to in Article 42 (1), Item 1, letter b) of the Higher Education Act in specialties within the professional area of public health and in nursing, midwifery, and medical assistant specialties from the professional area of health care shall be organised and conducted at departments and/or branches of higher schools accredited under the Higher Education Act.
(3) (Amended and supplemented, SG No. 85/2005, effective 1.09.2006, amended, SG No. 41/2007) The training for and acquisition of a Bachelor's degree under Article 42 (1), Item 1, letter a) of the Higher Education Act in specialties within the professional area of health care shall be organised and conducted at colleges accredited under the Higher Education Act.
(4) The training for the acquisition of a Doctor's degree in scientific specialisms within the field of healthcare shall be conducted at higher schools, the Bulgarian Academy of Sciences, national centres for public health affairs and other research organisations accredited under the Higher Education Act.

Article 176

(1) Upon receiving their diplomas, all medical doctors and doctors of dental medicine shall take the Hippocratic oath. The text of the oath shall be adopted by the Supreme Medical Council.
(2) (Supplemented, SG No. 85/2005) Nationals of EU Member States, the other member states of the European Economic Area and Switzerland, shall be provided an oath suitable in content and form.

Article 177

(Amended, SG No. 85/2005) The Council of Ministers shall adopt uniform state requirements to the acquisition of higher education in specialties of regulated profession from the professional areas of medicine, dental medicine, pharmacology and health care at the proposal of the Minister of Health.

Article 178

(1) (Amended, SG No. 41/2007, SG No. 103/2016) Post-graduate training shall be carried out for all holders of a Doctor's, Master's and Bachelor's degree working in the national healthcare system.
(2) Post-graduate training shall include:
1. the training for acquisition of a specialty in healthcare;
2. (amended, SG No. 85/2005) continuing medical training.
(3) The Minister of Health shall specify the number of places for post-graduate training in specialties subsidized by the government in conformity with the objectives and priorities of the national health strategy on an annual basis.

Article 179

(1) (Previous text of Article 179, amended, SG No. 98/2010, effective 1.01.2011) The Minister of Health shall plan, coordinate and supervise the activities related to the post-graduate training for the acquisition of a specialty by medical and non-medical specialists working in the national healthcare system.

(2) (New, SG No. 98/2010, effective 1.01.2011) The Minister of Health shall supervise the activities related to specialist training within the health care system in respect of higher education institutions, medical treatment facilities and health care facilities. Statements of findings, including recommendations and time limits for addressing irregularities, shall be drawn up within one month following their relevant inspections.

Article 180

(1) The theoretical training under Article 178, Item 1 of Paragraph (2), shall be conducted by:
1. higher schools accredited with positive assessment under the Higher Education Act and the Military Medical Academy;
2. national centres for public health affairs accredited for the respective specialty under the Higher Education Act.
(2) The practical training under Article 178 (2), item 1 shall be conducted by:
1. the facilities under Paragraph (1);
2. (amended, SG No. 102/2018, effective 1.01.2019) the medical treatment facilities which have received approval from the Minister of Health for the activities under Article 90, paragraph 1 of the Medical-Treatment Facilities Act.
(3) Specialty shall be acquired upon the completion of training programmes and successful sitting for a practical and theoretical examination before a state examination panel appointed by order of the Minister of Health.
(4) (New, SG No. 59/2010, effective 31.07.2010, repealed, SG No. 102/2018, effective 1.01.2019).

Article 181

(1) (Amended, SG No. 41/2009, effective 2.06.2009, SG No. 68/2013, effective 2.08.2013) The list of specialties in the healthcare system and the terms and conditions for conducting training and acquiring a specialty in healthcare, as well as financial matters, shall be set out in an ordinance issued by the Minister of Health in consultation with the Minister of Education and Science and the Minister of Finance.
(2) The funding of the training for acquiring a specialty in healthcare shall be determined in conformity with the objectives and priorities of the national health strategy.

Article 182

(1) (Amended, SG No. 85/2005, SG No. 75/2006, SG No. 103/2016) Doctors', dental practitioners', master pharmacists', nurses, midwives and associated medical specialists professional organisations shall organise, coordinate, conduct, register and control the continuing medical education of medical doctors, dental practitioners, master pharmacists, nurses, midwives and associated medical specialists under terms and by a procedure set out in agreements with the higher schools, the Bulgarian Red Cross and the Military Medical Academy.
(2) (Amended, SG No. 85/2005) Higher schools, the Military Medical Academy, medical colleges, the Bulgarian Red Cross Society and other associations of people working in healthcare shall conduct the continued medical training of specialists in the healthcare system other than those under Paragraph (1) under terms and conditions set out in agreements with the post-graduate training facilities.
(3) (Amended, SG No. 85/2005, SG No. 75/2006) The Union of Scientific Medical Societies in Bulgaria, the Union of Scientists in Bulgaria and medical associations by specialties may engage in the conduct of continuing medical training of medical doctors, doctors of dental medicine and master pharmacists under terms and conditions set out in agreements with the Bulgarian Medical Association, the Bulgarian Dental Association and Union of Pharmacists in Bulgaria.
(4) (Repealed, SG No. 103/2016).

Section II
Medical Profession

Article 183

(1) (Amended, SG No. 85/2005, SG No. 41/2009, effective 2.06.2009) The medical profession shall be practiced by persons who hold a diploma for completed higher education in specialties within the professional areas of medicine, dental medicine, pharmacology and health care.
(2) (New, SG No. 85/2005) The diploma referred to in Paragraph (1) shall attest to the higher education acquired in the respective specialty and educational qualification degree, as well as to the professional qualification as set down in the state requirements pursuant to Article 177.
(3) (Renumbered from Paragraph (2), SG No. 85/2005) Medical doctors and doctors of dental medicine shall practice the medical profession under the conditions of Paragraph (1) and Article 3 (1) of the Doctors and Dentists Professional Organisations Act.
(4) (New, SG No. 85/2005, amended, SG No. 91/2018) Nurses, midwives and associated medical specialists, dental technicians and pharmaceutical assistants shall practice the medical profession under the conditions referred to in Chapter Two of the Professional Organisations of Medical Nurses, Midwives and Associated Medical Specialists, Dental Technicians and Assistant Pharmacists Guild Act.
(5) (New, SG No. 75/2006) Master pharmacists shall practice the medical profession under the conditions of Paragraph (1) and Article 3 (1) of the Professional Organisation of Masters of Pharmacy Act.

Article 184

(Repealed, SG No. 85/2005).

Article 185

(1) (Amended, SG No. 85/2005, SG No. 41/2009, effective 2.06.2009) The Ministry of Health shall establish and maintain ex officio a list of persons who have acquired higher education in specialties from the professional field of medicine, dental medicine, pharmacology, public health and health care.
(2) (Repealed, renumbered from Paragraph (4), amended, SG No. 85/2005) The data in the list shall be accessible for use to all persons under the Access to Public Information Act.
(3) (Repealed, SG No. 85/2005, new, SG No. 98/2010, effective 1.01.2011, amended, SG No. 91/2018) The Bulgarian Medical Association, the Bulgarian Dental Association, the Bulgarian Pharmaceutical Association and the professional organizations within the meaning of the Professional Organisations of Medical Nurses, Midwives and Associated Medical Specialists, Dental Technicians and Assistant Pharmacists Guild Act shall provide the Ministry of Health with the following information submitted both in hard copy, as well as in electronic form:
1. registration and deregistration of persons with the register of the relevant professional organisation, within 30 days upon inscribing the changes in the register;
2. (amended, SG No. 27/2016) any administrative penalties imposed on members of the relevant professional organisation on the day following the entry into force of the penal order;
(4) (New, SG No. 98/2010, effective 1.01.2011) Upon request, the professional organisations under Paragraph 3 shall provide the Ministry of Health with information concerning the specialist training undergone by members of the relevant professional organisation under Article 178(2).
(5) (New, SG No. 98/2010, effective 1.01.2011, amended, SG No. 68/2013, effective 2.08.2013) By 31 January each year, as well as upon request, the Ministry of Education and Science and higher education institutions shall provide the Ministry of Health with information concerning previous year's graduates in the following professional areas: Medicine, Dental Medicine, Pharmacy, Public Health, and Health Care, as well as concerning the persons who have met the conditions under Article 186(3).
(6) (New, SG No. 98/2010, effective 1.01.2011) By 31 January each year, as well as upon request, institutions within the system of vocational education and training shall provide the Ministry of

Health with information concerning the persons who have obtained professional qualifications as a medical specialist.

Article 186

(Amended, SG No. 85/2005)

(1) (Amended, SG No. 13/2008) Citizens of a European Union member states, the other member states of the European Economic Area and Switzerland shall practice the medical profession in the Republic of Bulgaria after recognition of their professional qualifications according to the procedure established by the Recognition of Professional Qualifications Act.

(2) The Ministry of Health and the higher educational establishments shall provide the persons referred to in Paragraph (1) conditions for the acquisition of the necessary linguistic knowledge and professional terminology in Bulgarian for practicing their profession in the Republic of Bulgaria when the need arises and when this is in their interest and in the interest of their patients.

(3) (Amended, SG No. 59/2006, SG No. 13/2008, SG No. 98/2010, effective 14.12.2010) Foreigners other than those referred to in Paragraph 1 may practice the medical profession in the Republic of Bulgaria subject to the following conditions:

1. (amended, SG No. 68/2013, effective 2.08.2013) they have a command of the Bulgarian language and the professional terminology in Bulgarian, which is to be ascertained as per the procedure laid down in regulations issued by the Minister of Education and Science and the Minister of Health;

2. upon recognition of their professional qualifications as per the procedure laid down in the Recognition of Professional Qualifications Act, if the professional qualifications have been obtained in a Member State of the European Union; or

3. upon passing an examination, if the professional qualifications have been obtained in a third country, where the examination shall:

(a) include the state examinations set out in the unified state requirements under Article 177 concerning the pursuit of a regulated profession in the following professional areas: Medicine, Dental Medicine, Pharmacy, and Health Care;

(b) be the examination under Article 180(3) for practicing within the health care system.

(4) In the cases other than those under Paragraphs (1) - (3), the right to practice the medical profession shall be granted also to foreigners invited for scientific exchange between medical treatment facilities under terms and conditions set out in an ordinance issued by the Minister of Health.

(5) (Repealed, SG No. 13/2008, new, SG No. 98/2010, effective 14.12.2010) The conditions and procedures to sit for examinations under Paragraph 3, item 3 shall be determined by regulations of the Minister of Health.

(6) (New, SG No. 98/2010, effective 14.12.2010) The payment procedure as to the examination sitting under Paragraph Article 3, item (3) shall be laid down in the rules of procedure of the relevant higher education institution.

(7) (New, SG No. 98/2010, effective 14.12.2010) The higher education institution shall issue the certificate attesting that the examination under Paragraph 3, item 3 has been passed.

(8) (New, SG No. 27/2016) The Regulation referred to in Article 3(1) shall stipulate the rules and procedure for assessing Bulgarian language competence applicable to the persons referred to in paragraph 1.

Article 187

(Repealed, SG No. 85/2005).

Article 188

(Amended, SG No. 85/2005)

The Minister of Health shall issue an ordinance to specify the professional competence of persons working in the national healthcare system who are holders of a higher education diploma in the specialties of psychology, kinesitherapy, biology, biochemistry, microbiology and molecular biology.

Article 189

(1) (Previous text of Article 189, SG No. 98/2016, effective 1.01.2017) Medical treatment facilities shall insure the persons exercising the medical profession at the medical facility for potential damages resulting from culpable non-performance of their professional duties.

(2) (New, SG No. 98/2016, effective 1.01.2017) The terms and conditions, procedure, time-period for taking the insurance and the minimum insurance amount in the cases of mandatory insurance under Paragraph 1 shall be determined with an ordinance of the Council of Ministers.

Article 190

(1) Persons exercising the medical profession shall be free to act and make decisions in accordance with their professional qualifications, medical standards and medical ethics.

(2) Medical specialists and medical treatment facilities may not use commercial advertising for their activities.

Article 191

(Amended and supplemented, SG No. 85/2005, amended, SG No. 59/2006, repealed, SG No. 41/2009, effective 2.06.2009).

Article 192

(1) Medical specialists may not exercise their profession if they suffer of diseases threatening the health and life of patients.

(2) The list of diseases under Paragraph (1) shall be determined by the Minister of Health.

(3) In the cases under Paragraph (1), the Minister of Health shall issue an order to delete the medical specialist from the register under Article 185.

(4) (Supplemented, SG No. 77/2018, effective 1.01.2019) The order of the Minister of Health shall be subject to appeal before the relevant Administrative Court under the Code of Administrative Procedure.

(5) (New, SG No. 98/2010, effective 1.01.2011) The Ministry of Health shall send a certified copy of the order enforced under Paragraph 3 to the relevant professional association and regional health inspectorate.

Article 193

(1) The Minister of Health may issue an order to withdraw the right of a person to exercise the medical profession in the Republic of Bulgaria for a term ranging from six months to two years in any of the following cases:

1. recurring violation of the established medical standards;

2. recurring violation of the principles and procedure for conducting medical expert activities to establish the capability for work;

3. (new, SG No. 59/2010, effective 31.07.2010) recurring violation of the procedure for conducting medical expert examinations as referred to in Article 103, paragraph 3.

(2) (Supplemented, SG No. 77/2018, effective 1.01.2019) The order under Paragraph (1) shall be subject to appeal before the relevant Administrative Court under the Code of Administrative Procedure.

(3) (New, SG No. 98/2010, effective 1.01.2011) The Ministry of Health shall send a certified copy of the order enforced under Paragraph 1 to the relevant professional association and regional health inspectorate.

Section III
(Repealed, SG No. 13/2008)
Recognition of Professional Qualification in Medical Profession
(Title amended, SG No. 59/2006)

Article 194

(Amended and supplemented, SG No. 85/2005, amended, SG No. 59/2006, repealed, SG No. 13/2008).

Article 195

(Supplemented, SG No. 85/2005, amended and supplemented, SG No. 59/2006, repealed, SG No. 13/2008).

Article 196

(Repealed, SG No. 59/2006).

Section IV
Medical Research on People. Medical Science

Article 197

(1) The Ministry of Health shall organise and control the conduct of medical research on people.
(2) Medical research, within the meaning of this Act, is any experiment on people conducted with a view to increasing medical knowledge.
(3) Tested persons shall have all the rights of a patient.
(4) Medical research shall be conducted, while ensuring maximum safety for the health of the tested person and non-disclosing his/her personal data.
(5) The interests of the tested person shall prevail over the scientific and financial interests of the researcher at any stage of the medical research.

Article 198

(1) Medical research on people shall not be conducted in any of the following cases:
1. it contravenes the law or medical ethics;
2. no evidence has been produced on their safety;
3. no evidence has been produced on the expected scientific benefits;
4. it does not correspond to the scientific objective and the medical research plan;
5. there is an increased risk for the health and life of the tested person.
(2) No medical research on people shall be conducted with chemical substances and physical sources of radiation which may lead to changes of the human genome.
(3) No medical research on people shall be conducted with products of genetic engineering which may lead to the transmission of new properties of the progeny.

Article 199

(1) Medical research shall be conducted only on persons who have given their informed consent in writing upon their notification in writing by the leader of the research on the essence, importance, scope and possible risks of the research.
(2) Consent with the participation in medical research shall be given only by a legally capable person understanding the essence, importance, scope and possible risks of the clinical tests.
(3) The consent shall be given in person and in writing. It may be withdrawn at any point of time.

Article 200

(1) No medical research shall be conducted on people who have been put under legal incapacity.
(2) Where no significant health benefits are expected, medical research shall not be conducted on:
1. pregnant women and breast-feeding mothers;
2. prisoners;
3. (repealed, SG No. 46/2007, effective 1.01.2008).

Article 201

(Amended, SG No. 98/2010, effective 14.12.2010)
(1) The medical research head shall be jointly liable with the other individuals on the research team for any material and non-material damage they have caused to the medical research participants as a result of effects suffered during the medical research.
(2) The medical research head shall take out insurance covering the liability of both the head and the other individuals on the research team for any material and non-material damage suffered by the medical research participants as a result of effects caused during the medical research.

(3) The general terms and conditions, the minimum insurance amount, the minimum insurance premium and the insurance procedure under Paragraph 2 shall be set out in an ordinance issued by the Council of Ministers.

Article 202

(1) The leader of the medical research shall be a medical doctor or a doctor of dental medicine with recognised medical specialty and shall be responsible for the planning and conduct of the research.
(2) Medical research on people shall be conducted only by qualified specialists with higher education in the field of medicine, dental medicine, pharmacology, biology and biochemistry.
(3) Medical research may be conducted by foreign persons only on the basis of an agreement consulted with the Minister of Health.

Article 203

(1) Medical research shall be conducted upon obtaining a positive opinion from the local commission for ethics set up at the medical facility or research organisation conducting the medical research.
(2) The membership of the commission under Paragraph (1) shall be determined by the head of the facility or organisation.
(3) Specialists involved in the preparation, organisation and conduct of the research may not sit on the commission under Paragraph (1).
(4) The local commission for ethics shall give its opinion within 30 days of receipt of the request by the leader of the research.
(5) The local commission for ethics shall supervise the conduct of medical research on people, on which it has given a positive opinion.

Article 204

Upon the completion of the medical research on people, the leader of the research shall inform the local commission for ethics within 30 days.

Article 205

(1) The medical research may be terminated at any point of time in any of the following cases:
1. withdrawal of the consent of the tested person;
2. (new, SG No. 41/2009, effective 2.06.2009) where hazardous impact on the health of the tested person has been found;
3. (renumbered from Item 2, SG No. 41/2009, effective 2.06.2009) at the proposal of the leader of the research;
4. (renumbered from Item 3, SG No. 41/2009, effective 2.06.2009) at the proposal of the chairperson of the local commission for ethics at the medical or healthcare facility in the event of proven violations in the course of its conduct.
(2) Upon the termination of the medical research under Items 1 and 2 of Paragraph (1), the leader of the research shall inform the local commission for ethics within 15 days.
(3) (New, SG No. 41/2009, effective 2.06.2009, amended, SG No. 98/2010, effective 1.01.2011) In the cases falling under Paragraph (1), Item 2, the medical research shall be terminated by order of the RHI director under the terms and conditions laid down in the ordinance provided for in Article 206.

Article 206

(Amended, SG No. 74/2009, SG No. 68/2013, effective 2.08.2013) The terms and conditions for the conduct of medical research shall be set out in an ordinance issued by the Minister of Health in consultation with the Minister of Education and Science.

Article 207

The Minister of Health shall determine, on an annual basis, research projects in the government research priorities in the field of medicine at the proposal of the rectors of higher schools, the

directors of the national centres for public health affairs, heads of research organisations and other legal entities and upon obtaining the opinion of the Supreme Medical Council.

Article 208

(1) The Minister of Health shall announce a competition to select contractors of research projects in the government research priorities.

(2) (Amended, SG No. 68/2013, effective 2.08.2013) The terms and conditions for the conduct of competitions and the requirements to the applicants shall be set out in an ordinance issued by the Minister of Health in consultation with the Minister of Education and Science.

(3) Research projects shall be financed through government subsidies and other sources.

Article 208a

(New, SG No. 98/2010, effective 14.12.2010)

The body of a deceased person may be used for educational and scientific research purposes in higher medical schools, once the death has been established as per the medical criteria and procedures laid down in the regulations under Article 18(1) of the Organ, Tissue and Cell Transplantation Act.

Article 208b

(New, SG No. 98/2010, effective 14.12.2010)

(1) The body of a deceased person may be used for educational and scientific research purposes in higher medical schools, if the person is a Bulgarian national and had expressed explicit consent thereof while still alive.

(2) In the case of no consent under Paragraph 1, the body of a deceased person may be used for educational purposes in higher medical schools, upon obtaining, within a reasonably short time, the written consent of one of the following persons addressed in the same order as presented below:

1. spouse or cohabiting (common law) partner;
2. relatives in both the descending and ascending lines;
3. collaterals to the third degree of kinship;
4. relatives-in-law up to the second degree of kinship.

(3) In the case of no consent under Paragraph 1 and no statutory consent due to the lack of persons found under Paragraph 2, the body of a deceased person may also be used for educational and scientific research purposes.

(4) The procedures governing the use of bodies of deceased persons under Paragraphs 1 - 3 for educational and scientific research purposes in higher medical schools shall be laid down in regulations of the Minister of Health concerted with the Minister of Justice and the Minister of Interior.

Article 208c

(New, SG No. 98/2010, effective 14.12.2010)

(1) Upon completing the post-mortem educational activities, the higher medical schools shall notify the relatives of the deceased person and shall pay the funeral costs.

(2) Higher medical schools shall arrange and pay the costs for the funeral of the deceased person in the following cases:

1. when consent has been given under Article 208b(1) and no persons within the meaning of Article 208b(2) have been found;
2. under the circumstances of Article 208b(3).

Chapter Eight
ADMINISTRATIVE AND PENAL PROVISION

Article 209

(1) Persons failing to appear for a compulsory preventive medical examination, test or immunization shall be sanctioned by a fine ranging from BGN 50 to BGN 100 or from BGN 100 to BGN 200 in the case of recurring failure to appear.

(2) The penalties under Paragraph (1) shall be imposed also on officials who have prevented persons to appear for a compulsory preventive medical examination, test or immunization.
(3) Parents or custodians failing to ensure the compulsory immunization of their children shall be sanctioned by a fine ranging from BGN 50 to BGN 100. The fine shall range from BGN 100 to BGN 200 in the case of recurring violation.

Article 209a

(New, SG No. 28/2020, effective 13.03.2020)
(1) (Amended, SG No. 34/2020, effective 9.04.2020, SG No. 44/2020, effective 14.05.2020, SG No. 32/2022, effective 26.04.2022) Any person who violates or fails to comply with anti-epidemic measures referred to in Article 63 (4), (7), (10) or (11) and Article 63a (1) and (2) introduced by the Minister of Health or the Head of a Regional Health Inspectorate shall be punished by a fine of between BGN 300 and 1000 and, in the case of a repeat violation, of between BGN 1000 and 2000, unless the act constitutes a criminal offence.
(2) (Amended, SG No. 34/2020, effective 9.04.2020) Where the violation under Paragraph 1 has been committed by a sole proprietor or a legal entity, the pecuniary sanction imposed shall range from BGN 500 to BGN 2,000 or from BGN 2,000 to BGN 5,000 in the case of recurring violation.
(3) The violations under Paragraphs (1) and (2) shall be ascertained by written statements drawn up by State health inspectors or by officials designated by the director of the regional health inspectorate, officials designated by the directors of the regional directorates of the Ministry of Interior, or officials designated by the municipality mayors.
(4) The penalty decrees shall be issued, respectively, by the director of the relevant regional health inspectorate, the directorate of the relevant regional directorate of the Ministry of Interior, and the mayor of the relevant municipality.

Article 210

(1) (Amended, SG No. 98/2010, effective 1.01.2011) Persons engaging in activities in violation of the health requirements under this Act and the related secondary legislation shall be sanctioned by a fine ranging from BGN 100 to BGN 1,500, and in the case of recurring violation – from BGN 500 to BGN 5,000.
(2) (Amended, SG No. 98/2010, effective 1.01.2011) Where the violation under Paragraph (1) has been committed by a sole proprietor, the pecuniary sanction imposed shall range from BGN 200 to BGN 3000, and in the case of recurring violation – from BGN 1,000 to BGN 8,000.
(3) (Amended, SG No. 98/2010, effective 1.01.2011) Where the violation under Paragraph (1) has been committed by a legal person, the pecuniary sanction imposed shall range from BGN 1,000 to BGN 5,000, and in the case of recurring violation – from BGN 3,000 to BGN 12,000.

Article 211

(1) (Amended, SG No. 98/2010, effective 1.01.2011) Persons engaging in activities in a public use facility without fulfilling the obligation to notify the RHI thereof shall be sanctioned by a fine ranging from BGN 200 to BGN 3,000, and in the case of recurring violation – from BGN 1,000 to BGN 10,000.
(2) (Amended, SG No. 98/2010, effective 1.01.2011) Where the violation under Paragraph (1) has been committed by a sole proprietor, the pecuniary sanction imposed shall range from BGN 500 to BGN 9,000, and in the case of recurring violation – from BGN 2,000 to BGN 15,000.
(3) (Amended, SG No. 98/2010, effective 1.01.2011) Where the violation under Paragraph (1) has been committed by a legal person, the pecuniary sanction imposed shall range from BGN 2,000 to BGN 15,000, and in the case of recurring violation – from BGN 5,000 to BGN 20,000.

Article 212

(Amended, SG No. 98/2010, effective 1.01.2011)
(1) Whoever fails to comply with a prescription given by the state health control authorities shall be sanctioned by a fine ranging from BGN 200 to BGN 500, unless a more severe punishment is stipulated, and in the case of recurring violation – from BGN 500 to BGN 1,000.

(2) Where the violation under Paragraph (1) has been committed by a sole proprietor, the pecuniary sanction imposed shall range from BGN 500 to BGN 2,000 or from BGN 1,000 to BGN 3,000 in the case of recurring violation.
(3) Where the violation under Paragraph (1) has been committed by a legal person, the pecuniary sanction imposed shall range from BGN 1,000 to BGN 3,000 or from BGN 2,000 to BGN 5,000 in the case of recurring violation

Article 212a

(New, SG No. 98/2010, effective 1.01.2011)
(1) Whoever refuses to cooperate or obstructs the state health control, or sampling to be taken by the state health control authorities, shall be sanctioned by a fine ranging from BGN 200 to BGN 1,000, unless a more severe punishment is stipulated, and in the case of recurring violation -from BGN 1,000 to BGN 2,000.
(2) Where the violation under Paragraph (1) has been committed by a sole proprietor, the pecuniary sanction imposed shall range from BGN 1000 to BGN 3000 or from BGN 2000 to BGN 5000 in the case of recurring violation.
(3) Where the violation under Paragraph (1) has been committed by a legal person, the pecuniary sanction imposed shall range from BGN 2000 to BGN 5000 or from BGN 5000 to BGN 10,000 in the case of recurring violation.

Article 213

(1) (Amended, SG No. 98/2010, effective 1.01.2011) Persons failing to fulfil the instructions to discontinue the operation of facilities or violating a prohibition to sell products and goods as instructed by the state health control authorities shall be sanctioned by a fine ranging from BGN 2,000 to BGN 6,000, unless a more severe punishment is stipulated, and in the case of recurring violation - from BGN 6,000 to BGN 12,000.
(2) (Amended, SG No. 98/2010, effective 1.01.2011) Where the violation under Paragraph (1) has been committed by a sole proprietor, the pecuniary sanction imposed shall range from BGN 3,000 to BGN 9,000, and in the case of recurring violation - from BGN 10,000 to BGN 30,000.
(3) Where the violation under Paragraph (1) has been committed by a legal person, the pecuniary sanction imposed shall range from BGN 5000 to BGN 15000 or from BGN 15 000 to BGN 30 000 in the case of recurring violation.

Article 213a

(New, SG No. 1/2014, effective 3.01.2014)
(1) Persons placing cosmetic products on the market in violation of the requirements under Article 49(2), items (2), (3), (5), (6), (8), (9), (11) and (12) shall be punished with a fine of BGN 1,500, and in the case of recurring violation BGN 3,000.
(2) Where the violation under paragraph 1 is committed by a sole proprietor, the pecuniary sanction shall amount to BGN 3,000, and in the case of recurring violation BGN 6,000.
(3) Where the violation under paragraph 1 is committed by a legal person, the pecuniary sanction shall amount to BGN 6,000, and in the case of recurring violation BGN 12,000.

Article 213b

(New, SG No. 1/2014, effective 3.01.2014)
(1) Persons placing cosmetic products on the market in violation of the requirements under Article 49(1), items (1), (4), (7) and (10) shall be punished with a fine of BGN 1,000, and in the case of recurring violation BGN 2,000.
(2) Where the violation under paragraph 1 is committed by a sole proprietor, the pecuniary sanction shall amount to BGN 2,000 and in the case of recurring violation BGN 4,000.
(3) Where the violation under paragraph 1 is committed by a legal person, the pecuniary sanction shall amount to BGN 4,000 and in the case of recurring violation BGN 8,000.

Article 214

(1) (Amended, SG No. 59/2006, effective 21.07.2006) Persons engaging in unauthorised activities for the demolishing or removal of asbestos and/or asbestos-containing materials of buildings, structures, enterprises, installations or vessels without having received the permit referred to in Article 73 herein shall be sanctioned by a fine of up to BGN 1,500 or ranging from BGN 1,500 to BGN 3,000 in the case of recurring violation.

(2) Where the violation under Paragraph (1) has been committed by a sole proprietor, the pecuniary sanction imposed shall range from BGN 500 to BGN 1500 or from BGN 1500 to BGN 5000 in the case of recurring violation.

(3) Where the violation under Paragraph (1) has been committed by a legal person, the pecuniary sanction imposed shall range from BGN 1,000 to BGN 3,000, and in the case of recurring violation – from BGN 3,000 to BGN 6,000.

Article 215

(Supplemented, SG No. 98/2010, effective 14.12.2010, amended, SG No. 23/2020, effective 14.03.2020, SG No. 28/2020, effective 13.03.2020, SG No. 44/2020, effective 14.05.2020, SG No. 105/2020, effective 11.12.2020)

(1) Any patient having an infectious disease or any carrier of such referred to in Article 61(1) or (3) who refuses or interrupts the implementation of the mandatory isolation referred to in Article 61(4) or Article 61a(2) shall be punished by a fine to the amount of BGN 5,000.

(2) The hospital admission of any person referred to in Paragraph 1 who refuse to undergo mandatory isolation referred to in Paragraph 1 as well as of any person referred to in Paragraph 1 who interrupts the implementation of the mandatory isolation referred to in Paragraph 1 shall be effected with the assistance of the authorities of the Ministry of Interior on request by the state health control authorities, the head of the medical facility for hospital care, the treating physician or the physician who has referred the person for a hospital stay.

Article 215a

(New, SG No. 28/2020, effective 13.03.2020)

(1) (Amended, SG No. 44/2020, effective 14.05.2020, supplemented, SG No. 105/2020, effective 11.12.2020) Any contact person referred to in Article 61(8) herein, who refuses to submit to a test for the purpose of establishing the fact whether the said person is a carrier of an infectious disease, shall be punished by a fine ranging from BGN 50 to BGN 500.

(2) The testing of any person referred to in Paragraph 1, who refuses to present himself or herself for a test, shall be compelled with the assistance of the authorities of the Ministry of Interior at the request of the State health control authorities.

Article 215b

(New, SG No. 44/2020, effective 14.05.2020)

(1) Any person who has had contact with a patient having an infectious disease referred to in Article 61(1) or (3) and any person who has arrived on the territory of Bulgaria from another country that refuses, or fails, to comply with the mandatory quarantine requirements set out in Article 61(6) shall be punished by a fine to the amount of BGN 5,000.

(2) Any person referred to in Paragraph (1) who fails to comply with mandatory quarantine requirements shall be compelled with the assistance of the authorities of the Ministry of Interior on request by the state health control authorities.

Article 216

Medical specialists violating the terms and conditions for registration, notification and reporting, as well as the terms and conditions for isolation, testing and dispensary registration of patients, former patients, infection carriers and persons in contact with them shall be sanctioned by a fine ranging from BGN 300 to BGN 1,000 and with withdrawal of the right to exercise the medical profession for a term ranging from six months to a year in the case of recurring violation.

Article 217

(1) Persons engaging in activities for disinfection, pest control of insects and rodents in violation of the requirements under this Act and the related secondary legislation shall be sanctioned by a fine ranging from BGN 500 to BGN 1,500, and in the case of recurring violation – from BGN 1,500 to BGN 3,000.

(2) Where the violation under Paragraph (1) has been committed by a sole proprietor, the pecuniary sanction imposed shall range from BGN 300 to BGN 1,000 or from BGN 1,000 to BGN 3,000 in the case of recurring violation.

(3) Where the violation under Paragraph (1) has been committed by a legal person, the pecuniary sanction imposed shall range from BGN 500 to BGN 1,500 or from BGN 1,500 to BGN 5,000 in the case of recurring violation.

Article 218

(1) (Amended, SG No. 40/2012, effective 1.06.2012) Persons violating the provisions of Articles 54, 56 or 56a shall be sanctioned by a fine ranging from BGN 300 to BGN 500, and in the case of recurring violation - from BGN 500 to BGN 1,000.

(2) (New, SG No. 41/2009, effective 2.06.2009, amended, SG No. 40/2012, effective 1.06.2012, SG No. 58/2019) Anyone who tolerates, in a site or facility managed thereby, the commission of a violation covered by Articles 54, 56 or 56a shall be punished by a fine of between BGN 300 and BGN 500, with a pecuniary penalty of between BGN 1,000 and BGN 1,500 when the violation has been committed by a sole trader, or by a pecuniary penalty of between BGN 3,000 and BGN 5,000 when the violation has been committed by a legal person.

(2a) (New, SG No. 62/2022, effective 5.08.2022) Anyone who violates Article 54a shall be sanctioned by a fine ranging from BGN 800 to BGN 1,500, and in the case of recurring violation – from BGN 1,500 to BGN 3,000. When the violation of Article 54a has been committed by a sole trader or by a legal entity, a pecuniary penalty ranging from BGN 3,000 to BGN 6,000, and in the case of recurring violation – from BGN 5,000 to BGN 12,000 shall be imposed.

(3) (Supplemented, SG No. 59/2006, renumbered from Paragraph 2, SG No. 41/2009, effective 2.06.2009, amended, SG No. 40/2012, effective 1.06.2012, SG No. 58/2019) In case of a repeated violation of Paragraph(2), a fine of between BGN 500 to BGN 1,000 or a property sanction of between BGN 1,500 and BGN 3,000 for sole traders and of between BGN 5,000 and BGN 10,000 shall be imposed.

(4) (Renumbered from Paragraph 3, SG No. 41/2009, effective 2.06.2009, amended, SG No. 40/2012, effective 1.06.2012) Persons advertising alcoholic beverages in violation of Article 55(1) and (2) shall be sanctioned by a fine ranging from BGN 1,500 to BGN 3,000, and in the case of recurring violation - from BGN 3,000 to BGN 5,000.

(5) (Renumbered from Paragraph 4, SG No. 41/2009, effective 2.06.2009, amended, SG No. 40/2012, effective 1.06.2012) Where the violation under Paragraph (4) has been committed by a sole proprietor, the pecuniary sanction imposed shall range from BGN 3,000 to BGN 10,000, and in the case of recurring violation - from BGN 10,000 to BGN 30,000.

(6) (Renumbered from Paragraph 5, SG No. 41/2009, effective 2.06.2009, amended, SG No. 40/2012, effective 1.06.2012) Where the violation under Paragraph 4 has been committed by a legal entity, the pecuniary sanction imposed shall range from BGN 10,000 to BGN 30,000, and in the case of recurring violation - from BGN 30,000 to BGN 50,000.

(7) (Renumbered from Paragraph 6, SG No. 41/2009, effective 2.06.2009) Radio and television operators broadcasting advertisement of alcoholic beverages in violation of Article 55(1) and (3) shall be sanctioned by a pecuniary sanction of BGN 5,000, and in the case of recurring violation - BGN 10,000, as imposed by the Council for Electronic Media under the Radio and Television Act.

(8) (Renumbered from Paragraph 7, SG No. 41/2009, effective 2.06.2009) Radio and television operators broadcasting advertisement of spirits in violation of Article 55, Paragraph (2) shall be punished pursuant to the Radio and Television Act.

Article 218a

(New, SG No. 42/2010, effective 2.06.2010, repealed, SG No. 40/2012, effective 1.06.2012).

Article 219

(1) Persons engaging in activities with sources of ionizing radiation in violation of the requirements under this Act and the related secondary legislation shall be sanctioned by a fine ranging from BGN 2,000 to BGN 5,000, or from BGN 5,000 to BGN 15,000 in the case of recurring violation.

(2) Where the violation under Paragraph (1) has been committed by a sole proprietor, the pecuniary sanction imposed shall range from BGN 1,000 to BGN 3,000 or from BGN 3,000 to BGN 10,000 in the case of recurring violation.

(3) Where the violation under Paragraph (1) has been committed by a legal person, the pecuniary sanction imposed shall range from BGN 1,500 to BGN 5,000 or from BGN 5,000 to BGN 15,000 in the case of recurring violation.

Article 220

(1) Officials failing to inform the patient of the circumstances under Article 88 (1) shall be sanctioned by a fine ranging from BGN 300 to BGN 1,000 and with withdrawal of the right to exercise the medical profession for a term ranging from six months to a year in the case of recurring violation.

(2) Persons providing medical aid without the informed consent of the patient or in violation of the requirements for obtaining the informed consent of the patient shall be sanctioned by a fine ranging from BGN 500 to BGN 1,500 and with withdrawal of the right to exercise the medical profession for a term ranging from six months to a year in the case of recurring violation.

(3) Officials disclosing health information beyond the provisions of this Act and the related secondary legislation shall be sanctioned by a fine ranging from BGN 500 to BGN 1,500 or from BGN 2,000 to BGN 6,000 in the case of recurring violation, unless a more severe punishment is due.

Article 221

(Amended, SG No. 101/2009, effective 1.01.2010)

(1) Any medical treatment facility which violates patient's rights regulated by this Act, as well as the related secondary legislation governing the Act's application, shall be sanctioned by a fine ranging from BGN 300 to BGN 1,000, or from BGN 500 to BGN 1,500 in the case of recurring violation.

(2) Where the violation under Paragraph (1) has been committed by a medical treatment facility which is a sole trader or a legal person, the pecuniary sanction shall range from BGN 500 to BGN 1,500, or from BGN 1,000 to BGN 3,000 in the case of recurring violation.

Article 221a

(New, SG No. 41/2009, effective 2.06.2009)

Any medical professional who does not meet an obligation provided for in Article 125a shall be sanctioned by a fine ranging from BGN 300 to BGN 1,000 or with debarring from practicing the medical profession for a period ranging from 6 months to one year.

Article 222

(1) (Amended, SG No. 85/2005, SG No. 59/2006) Persons providing medical aid or engaging in healthcare activities without having the necessary professional qualification in a medical profession required shall be sanctioned by a fine ranging from BGN 5,000 to BGN 10,000 or from BGN 10,000 to BGN 20,000 in the case of recurring violation, unless a more severe punishment is due.

(2) Medical specialists committing recurrent violations in the course of exercising the medical profession due to negligence or ignorance, committing gross mistakes in the job or engaging in immoral actions abusing with their official position shall be sanctioned by withdrawal of the right to exercise the medical profession for a term ranging from three months to two years, unless a more severe punishment is due.

(3) Medical doctors, doctors of dental medicine, nurses, midwives or paramedics refusing to provide urgent medical aid to a person in critical condition shall be sanctioned by a fine ranging from BGN 1,000 to BGN 5,000 and with withdrawal of the right to exercise the medical profession for a term ranging from three months to a year in the case of recurring violation.
(4) (New, SG No. 41/2009, effective 2.06.2009) Any national or executive consulting expert who refuses to fulfil or intentionally fails to fulfil an obligation assigned to them shall be sanctioned by a fine ranging from BGN 1,000 to BGN 3,000 or from BGN 3,000 to BGN 5,000 in the case of recurring violation.

Article 223

(Amended, SG No. 71/2006, effective 1.01.2007)
(1) Persons engaging in assisted reproduction in violation of Articles 130, 131, 132a, 132b, 133, 135 and 136 shall be sanctioned by a fine of BGN 15,000 or exceeding this sum but not exceeding BGN 50,000 and with withdrawal of the right to exercise the medical profession for a term ranging from three months to a year in the case of recurring violation, unless a more severe punishment is due.
(2) Persons who violate the provision of Article 132 shall be sanctioned by a fine of BGN 5,000 or exceeding this sum but not exceeding BGN 10,000 and a pecuniary sanction of BGN 20,000 or exceeding this sum but not exceeding BGN 50,000 shall be imposed in cases where the violation is perpetrated by a legal person.
(3) Persons who violate the provision of Article 134 shall be sanctioned by a fine of BGN 25,000 or exceeding this sum but not exceeding BGN 50,000 and a pecuniary sanction of BGN 50,000 or exceeding this sum but not exceeding BGN 100,000 shall be imposed in cases where the violation is perpetrated by a legal person.

Article 224

Officials imposing physical constraint measures to a patient with established mental disorders in violation of the requirements of this Act and the related secondary legislation shall be sanctioned by a fine ranging from BGN 500 to BGN 1,500 and with withdrawal of the right to exercise the medical profession for a term ranging from three months to a year in the case of recurring violation, unless a more severe punishment is due.

Article 225

(1) Medical specialists issuing sickness certificates in violation of the existing statutory requirements shall be sanctioned by a fine ranging from BGN 1,000 to BGN 3,000 or from BGN 4,000 to BGN 10,000 in the case of recurring violation.
(2) (Amended, SG No. 98/2010, effective 1.01.2011) Officials failing to fulfil the order of the RHI director to set up a physician consultative commission shall be sanctioned by a fine ranging from BGN 500 to BGN 1,500 or from BGN 1,500 to BGN 4,500 in the case of recurring violation.

Article 226

Persons engaging in medical research in violation of this Act shall be sanctioned by a fine ranging from BGN 2,000 to BGN 6,000 and with withdrawal of the right to exercise the medical profession for a term ranging from three months to a year in the case of recurring violation, unless a more severe punishment is due.

Article 227

Persons practising non-conventional methods of impact on individual health in violation of the requirements of this Act and the related secondary legislation shall be sanctioned by a fine ranging from BGN 500 to BGN 1,500 or from BGN 1,500 to BGN 5,000 in the case of recurring violation.

Article 228

Medical specialists violating the requirements under this Act and the related secondary legislation to the form, content, terms and conditions for the use, processing, analysis, storage and disclosure of

medical records shall be sanctioned by a fine ranging from BGN 500 to BGN 1,500 or from BGN 1,500 to BGN 3,000 in the case of recurring violation.

Article 228a

(New, SG No. 41/2009, effective 2.06.2009)

(1) (Amended, SG No. 15/2013, effective 1.01.2014) A pecuniary sanction ranging from BGN 5,000 to BGN 15,000 or from BGN 15,000 to BGN 25,000, in the case of recurring violation, shall be imposed on any medical facility which violates the procedure for spending the resources provided to it from the state budget pursuant to Article 82.

(2) (Amended, SG No. 15/2013, effective 1.01.2014) A pecuniary sanction ranging from BGN 3,000 to BGN 10,000 or from BGN 10,000 to BGN 20,000, in the case of recurring violation, shall be imposed on any medical facility which violates the procedure for prescribing and dispensing medicinal products purchased using resources from the state budget pursuant to Article 82.

Article 228b

(New, SG No. 41/2009, effective 2.06.2009, repealed, SG No. 102/2018, effective 1.04.2019).

Article 228c

(New, SG No. 98/2010, effective 1.01.2011)

(1) Any official who violates the conditions and procedures for holding and financing specialist training within the health care system laid down in the regulations under Article 181(1) shall be sanctioned by a fine ranging from BGN 500 to BGN 1,500, and in the case of recurring violation - from BGN 1,500 to BGN 3,000.

(2) Where the violation under Paragraph 1 has been committed by medical treatment or health care facility or by a regional health inspectorate, the pecuniary sanction shall range from BGN 2,000 to BGN 3,000; in cases of recurring violations, the fine shall amount from BGN 3,000 to BGN 6,000.

Article 229

(1) (Amended, SG No. 41/2009, effective 2.06.2009, SG No. 98/2010, effective 1.01.2011) Persons violating the requirements under this Act and the related secondary legislation in the cases other than those under Arts. 209 to 228c shall be sanctioned by a fine ranging from BGN 100 to BGN 600 or from BGN 500 to BGN 3,000 in the case of recurring violation.

(2) Where the violation under Paragraph (1) has been committed by a sole proprietor, the pecuniary sanction imposed shall range from BGN 200 to BGN 600 or from BGN 600 to BGN 2,000 in the case of recurring violation.

(3) Where the violation under Paragraph (1) has been committed by a legal person, the pecuniary sanction imposed shall range from BGN 500 to BGN 2,000 or from BGN 2,000 to BGN 5,000 in the case of recurring violation.

Article 229a

(New, SG No. 71/2006, effective 1.01.2007, amended, SG No. 98/2010, effective 14.12.2010, SG No. 102/2018, effective 1.04.2019) The presence of any violations referred to in Article 223, Paragraphs 1 and 2 shall be established by acts drafted by officials appointed by the Executive Director of the Medical Surveillance Executive Agency. Penal decrees shall be issued by the Executive Director of the Medical Surveillance Executive Agency.

Article 229b

(New, SG No. 71/2006, effective 1.01.2007, amended, SG No. 98/2010, effective 14.12.2010, SG No. 102/2018, effective 1.04.2019) Violations under Article 223(3) shall be established by memoranda compiled by the customs authorities or by officials from the Medical Supervision Executive Agency appointed by the executive director thereof, and the penalty orders shall be issued by the Director of the Customs Agency or officials appointed thereby, respectively by the executive director of the Medical Supervision Executive Agency or by an official authorised thereby.

Article 230

(1) (Amended, SG No. 98/2010, effective 1.01.2011) Violations under Articles 225 and 227 shall be established by statements of findings drawn up by state health inspectors or officials designated by the RHI director, and penalty orders shall be issued by the RHI director.

(2) A copy of the penalty order issued for violations under Paragraph (1) shall be send to the higher-standing medical expert body for assessment of the capacity for work, to the regional council for control of the acts issued by the medical expert bodies for assessment of short-term incapacity for work, to the parties concerned (assessed persons, insurers and the National Insurance Institute) and RHIF.

Article 231

(Amended, SG No. 41/2009, effective 2.06.2009, SG No. 98/2010, effective 1.01.2011, SG No. 40/2012, effective 1.06.2012)

(1) Violations under Articles 209 to 217, shall be established by statements of findings drawn up by state health inspectors or officials designated by the RHI director, and penalty orders shall be issued by the RHI director.

(2) Violations under Article 218 (1) - (6) shall be established by statements of findings drawn up by state health inspectors from regional health inspectorates and/or by state health inspectors from the Ministry of Health, and penalty orders shall be issued by the RHI director or, respectively, the Minister of Health.

Article 232

(Repealed, SG No. 98/2010, effective 1.01.2011).

Article 233

(Amended, SG No. 98/2010, effective 1.01.2011)

Violations under Article 219 shall be established by statements of findings drawn up by state health inspectors or by officials designated by the RHI director or the NCRRP director, and penalty orders shall be issued by the director of the respective RHI or the NCRRP director, respectively.

Article 233a

(New, SG No. 98/2010, effective 1.01.2011, amended, SG No. 102/2018, effective 1.04.2019) The violations under Articles 220, 221, 224, 226 and 228a shall be ascertained by statements issued by officials nominated by the Executive Director of the Medical Supervision Executive Agency, and penalty decrees shall be issued by the Executive Director of the Medical Supervision Executive Agency.

Article 234

(Amended, SG No. 41/2009, effective 2.06.2009, SG No. 98/2010, effective 1.01.2011)

Violations under Articles 221a and 222 shall be established by statements of findings drawn up by state health inspectors or officials designated by the RHI director, and penalty orders shall be issued by the RHI director.

Article 234a

(New, SG No. 98/2010, effective 1.01.2011, amended, SG No. 102/2018, effective 1.04.2019) Violations under Article 228 shall be established by statements of findings drawn up by state health inspectors or by officials designated by the RHI director or the Executive Director of Medical Supervision Executive Agency, and penalty orders shall be issued by the RHI director or the Executive Director of Medical Supervision Executive Agency.

Article 234b

(New, SG No. 98/2010, effective 1.01.2011)

Violations under Articles 228c shall be established by statements of findings drawn up by officials authorised by the Minister of Health, and penalty orders shall be issued by the Minister of Health.

Article 235

(Amended, SG No. 41/2009, effective 2.06.2009, SG No. 98/2010, effective 1.01.2011, SG No. 102/2018, effective 1.04.2019) Violations under Article 229 shall be established by statements of findings drawn up by state health inspectors or by officials designated by the RHI director or the Executive Director of Medical Supervision Executive Agency, and penalty orders shall be issued by the RHI director or the Executive Director of Medical Supervision Executive Agency.

Article 235a

(New, SG No. 107/2014, effective 1.01.2015)

(1) Anyone who violates the provisions of the instrument of the Council of Ministers under Article 103a shall be punished by a fine of BGN 100 or exceeding this amount but not exceeding BGN 500 for each individual case. The fine for repeating the same violation shall be double the amount initially imposed.

(2) Any head of a medical treatment facility, who violates his/her obligations in relation to the organisation of the activities for provision of data to the register under Article 33, Paragraph (5), Item 12 of the Social Insurance Code, set out in the ordinance under Article 101, Paragraph (7) herein, shall be punished by a fine of BGN 100 or exceeding this amount but not exceeding BGN 500 for each individual case. The fine for repeating the same violation shall be double the amount initially imposed.

(3) Violations under Paragraphs 1 and 2 shall be ascertained with instruments drawn up by the control bodies of the National Social Security Institute, and penal decrees shall be issued by the head of the territorial unit of the National Social Security Institute or an official authorised thereby.

Article 236

The drawing up of statements of findings and the issuance, appeal and enforcement of penalty orders shall be performed pursuant to the provisions of the Administrative Violations and Sanctions Act.

SUPPLEMENTARY PROVISIONS
(Title amended, SG No. 42/2010, effective 2.06.2010)

§ 1. Within the meaning of this Act:

1. "Medical records" is all forms of registration and storage of health information;
2. "Dispensary registration" is a method of active search for and diagnostics, treatment and regular monitoring of patients with specific diseases.
3. "Invasive methods" and diagnostic and therapeutic instrumental methods of penetration into the human body by means of severing of the skin and mucous membranes or through natural openings.
4. "Medical legal procedures" are procedures applied with a view to protecting the security of the country, the internal order or the health of citizens without any medical indications.
5. "Recurring violation" is a violation committed within a year of the effective date of the penalty order imposing a penalty for a violation of the same type.
6. "Screening" is a targeted preventive test within the framework of a specific programme to detect the spread of a certain sign, symptom or disease among a group of individuals.
7. "Physical constraint" is the application of mechanical means for immobilization, forced isolation in special closed premises and use of pharmaceuticals to reduce the physical activity of a patient, where the latter is a threat to himself/herself or the people around him/her.
8. "Health promotion" is a process, in which social, economic, environmental and other conditions are created and adequate health education is provided in order to enable individuals to improve their own health through enhanced individual and group responsibility.
9. "Public use facilities" are:

(a) (amended, SG No. 41/2009, effective 2.06.2009) water sources and mineral water sources, water supply facilities and installations for supply of drinking water to households;

(b) swimming pools, beaches, baths;

(c) (amended, SG No. 94/2005, supplemented, SG No. 41/2009, effective 2.06.2009, amended, SG No. 30/2013, effective 26.03.2013) tourist accommodations: hotels, motels, apartment tourism

complexes, cottage villages, tourism complexes, villas, family hotels, hostels, boarding houses, holiday accommodations belonging to the residents' employer, guest rooms, guest apartments, guest houses, bungalows, camp-sites, as well as tourist huts, tourist training centres and tourist dormitories;
(d) sports facilities - stadiums, sports halls, playgrounds, fitness centres and halls;
(e) (supplemented, SG No. 41/2009, effective 2.06.2009) theatre halls, cinema halls, concerts halls, community centres, computer and Internet halls, game halls;
(f) (supplemented, SG No. 41/2009, effective 2.06.2009, amended, SG No. 30/2013, effective 26.03.2013) barbers' shops, hairdressers' and beauty salons, tanning studios, tattoo and piercing studios, hydrotherapeutic (medical SPA) centres. SPA centres, wellness centres and thalassotherapeutic centres, public baths, launderettes, saunas, public WC;
(g) cemetery parks;
(h) (supplemented, SG No. 81/2006, amended, SG No. 46/2007, effective 12.06.2007, SG No. 98/2010, effective 14.12.2010) facilities for the production of and wholesale trade in medicinal products and medical devices, pharmacies, drugstores and opticians' shops;
(i) (amended, SG No. 41/2009, effective 2.06.2009, SG No. 98/2010, effective 14.12.2010) enterprises facilities for the production and storage of and trade in cosmetic products;
(j) railway stations, airports, ports, bus stations, underground stations;
(k) (amended, SG No. 41/2009, effective 2.06.2009) the facilities referred to in Article 26 (1), Item 3;
(l) (amended, SG No. 8/2011, effective 25.01.2011) public transport vehicles - trains, aircraft, ships, buses, trams, trolleybuses, underground trams, special vehicles - sanitary vehicles for patients, medicines and consumables, hearses;
(m) (supplemented, SG No. 94/2005, SG No. 41/2009, effective 2.06.2009, SG No. 98/2010, effective 14.12.2010, amended, SG No. 8/2011, effective 25.01.2011) facilities for production of bottled natural mineral, spring and table waters;
(n) (supplemented, SG No. 41/2009, effective 2.06.2009, amended, SG No. 24/2019, effective 1.07.2020 - amended, SG No. 101/2019) crèches and kindergartens, schools and higher schools, student hostels, schools in music, foreign languages and sports facilities for leisure and tourism of children and students, and centres for work with children;
(o) (amended, SG No. 59/2006, supplemented, SG No. 41/2009, effective 2.06.2009) medical and healthcare facilities, healthcare offices and the facilities offering unconventional methods for favourable impact on individual health;
(p) (repealed, SG No. 59/2006);
(q) sites with sources of ionizing radiation;
(r) (repealed, SG No. 82/2007);
(s) agricultural pharmacies;
(t) (new, SG No. 98/2010, effective 14.12.2010) facilities with radiating equipment which is part of an electronic telecommunication network, including: radio base stations and radio towers; radio and television receivers and repeaters; radio location and navigation stations and; other equipment.
10. "Products and goods of importance for human health" are:
(a) (amended, SG No. 8/2011, effective 25.01.2011) facilities for production of bottled natural mineral, spring and table waters;
(b) (amended, SG No. 98/2010, effective 14.12.2010) medicinal products;
(c) cosmetic products;
(d) (amended, SG No. 41/2009, effective 2.06.2009) chemical substances, preparations;
(e) second-hand clothes;
(f) (new, SG No. 41/2009, effective 2.06.2009) sanitary and hygienic materials (sanitary napkins, tampons, disposable baby diapers and disposable adult diapers, wet wipes).
(g) (new, SG No. 98/2010, effective 14.12.2010) medical devices.
11. "Activities of importance to human health" are:
(a) urban planning and development;

(b) the design, construction, reconstruction, extension and commissioning of housing units and public use facilities;
(c) cleaning of settlements in municipalities;
(d) the implementation of the immunization calendar of the Republic of Bulgaria;
(e) the prevention and restriction of internal hospital infections at medical treatment facilities;
(f) the implementation of disinfection, pest control of insects and rodents;
(g) the preparation and observance of weekly school programmes;
(h) the observance of physiological standards for the organised nutrition of groups of the population;
(i) (new, SG No. 59/2006) the activity of the services on labour medicine;
(j) (new, SG No. 59/2006, supplemented, SG No. 41/2010) activity with hazardous waste from medical and healthcare facilities;
(k) (new, SG No. 41/2009, effective 2.06.2009) compliance with the requirements for providing healthy nutrition to certain population subgroups;
(l) (new, SG No. 98/2010, effective 14.12.2010) operations involving asbestos and/or asbestos-containing materials;
(m) (new, SG No. 8/2011, effective 25.01.2011) exercising control in respect of the compliance with prohibitions and limitations laid down in statutory instruments as to the advertising and sale of alcoholic beverages;
(n) (new, SG No. 8/2011, effective 25.01.2011) exercising control in respect of the compliance with prohibitions and limitations for smoking.
12. "Environmental factors" are:
(a) drinking water and water for household purposes;
(b) water for bathing;
(c) mineral water for drinking or use for preventive, therapeutic or sanitary purposes;
(d) noise and vibrations in housing and public buildings and urban areas;
(e) ionizing radiation in housing, industrial and public buildings;
(f) (amended, SG No. 41/2009, effective 2.06.2009) non-ionizing radiation in housing, industrial and community buildings and urbanised territories;
(g) chemical factors and biological agents in public use facilities;
(h) resort resources;
(i) air.
13. "Urban areas" are settlements and communities within building boundaries set out in a specific development plan.
14. (Amended, SG No. 1/2014, effective 3.01.2014) "Cosmetic product" means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.
15. "Informed consent" is the consent given voluntarily after becoming aware of specific information.
16. "reproductive health" is the health of people in connection with their ability to have progeny.
17. "Alcoholic beverages" are spirits, wine and beer.
18. "Spirits" are liquids for consumption with at least 15 volumetric percent of ethyl alcohol.
19. "Direct advertising" is any form of a commercial message, communication or recommendation aimed at promoting alcoholic beverages and/or their consumption through the use of the beverages themselves or actions related to their consumption, production and distribution.
20. (Amended, SG No. 98/2010, effective 14.12.2010) "Indirect advertising" is any form of a commercial message, communication, recommendation or action using a name or brand of an alcoholic beverage, as well as the company name or brand of a producer of alcoholic beverages on products and goods which are not alcoholic beverages.

21. "Assisted reproduction" is the set of diagnostic and therapeutic methods intended to overcome sterility, which are applied at specialised centres.
22. "Dietetics" is a curative method by means of which a prescribed nutrition regime, including the one only with fruit, vegetables or other products of organic origin, leads to favourable impact on individual health.
23. "Curative hunger" is a curative method by means of which a prescribed regime of water, juices or other liquids intake leads to favourable impact on individual health.
24. (New, SG No. 71/2006, effective 1.01.2007) "Egg" is a female reproductive cell.
25. (New, SG No. 71/2006, effective 1.01.2007) "Sperm" are the male reproductive cells.
26. (New, SG No. 71/2006, effective 1.01.2007) "Zygote" is a fertilized egg in the stage of division.
27. (New, SG No. 71/2006, effective 1.01.2007) "Removal" is the extraction of eggs by medical methods or the collection of sperm from a donor, which is done with the objective of assisted reproduction or for other scientific and educational needs of medicine.
28. (New, SG No. 71/2006, effective 1.01.2007) "Implantation" is the placement by medical methods of sperm, an egg or a zygote in the body of a woman.
29. (New, SG No. 71/2006, effective 1.01.2007) "Expert examination" is an activity related to tests for assessing the condition of an egg, sperm or a zygote, as well as for establishing the existence of pathogenic organisms, chemical or biological substances through which an illness, infection or intoxication may be transmitted.
30. (New, SG No. 71/2006, effective 1.01.2007) "Processing" is an activity for preparation of an ovum, sperm or a zygote for placement by the application of physical, chemical or biological methods, in the course of extraction or directly after that, including the packaging thereof, at which no change to their integrity takes place.
31. (New, SG No. 71/2006, effective 1.01.2007) "Preservation" is an activity related to the application of physical or chemical processes, or change to the environment, for the prevention or delay of the biological or physical damage of the extracted eggs, sperm or zygotes, including the packaging thereof.
32. (New, SG No. 71/2006, effective 1.01.2007) "Donor" is every source of cells of human origin.
33. (New, SG No. 71/2006, effective 1.01.2007) "Labelling" is an activity on designation of the packaging of organs, tissues and cells with the objective of identification thereof.
34. (New, SG No. 41/2009, effective 2.06.2009, amended, SG No. 58/2022, effective 1.01.2023) "Short-term incapacity for work" is any condition where the insured person cannot or is unable to work due to an acute, sub-acute or exacerbated chronic disease; accident; occupational disease; treatment abroad; sanatorium and resort treatment; exigent medical examination or test; quarantine; suspension from work ordered by the medical authorities; attending on a family member who is either sick or under quarantine; need to take a sick family member to a medical examination; testing or treatment in the same settlement or other, in the country or abroad; pregnancy and parturition; attending on a healthy child aged up to 12 years suspended from a day care centre or school due to a quarantine at the centre or the school, or of a separate group or class in it, or due to quarantine of the child.
35. (New, SG No. 41/2009, effective 2.06.2009) "Long-term limited capability for work" is any condition where due to a chronic traumatic or non-traumatic injury (disease) the person has a limited capability for work in relation to a long-term functional deficit of a given impaired organ or system.
36. (New, SG No. 41/2009, effective 2.06.2009) "Type and extent of disability" is any condition of chronic traumatic or non-traumatic injury (disease) where the person not of working-age has a long-term functional deficit of a given impaired organ or system.
37. (New, SG No. 41/2009, effective 2.06.2009) "A person entrusted with raising the child" is a family member, relative, foster parent, head of an institution for raising and instructing children where they are permanently removed from their family with a judgment of the court ruling that the child be accommodated outside its family.

38. (New, SG No. 42/2010, effective 2.06.2010, repealed, SG No. 40/2012, effective 1.06.2012, new, SG No. 1/2014, effective 3.01.2014) "Manufacturer of cosmetic products" means any natural or legal person who manufactures a cosmetic product or has such a product designed or manufactured, and markets that cosmetic product under his name or trademark.
39. (New, SG No. 1/2014, effective 3.01.2014) "Distributor of cosmetic products" means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a cosmetic product available within the territory of the Member States of the European Union;
40. (New, SG No. 1/2014, effective 3.01.2014) "Importer of cosmetic products" means any natural or legal person established within the territory of the Member States of the European Union, who places a cosmetic product from a third country on the Community market;
41. (New, SG No. 1/2014, effective 3.01.2014) "Responsible person" means the manufacturer or his authorized representative established within the territory of a Member State of the European Union, the importer or his authorized representative established within the territory of a Member State of the European Union, and the distributor, making available on the market a cosmetic product with his name or trademark or changing a product already available on the market in a way which may affect the compliance with the applicable requirements of Regulation (EC) No. 1223/2009.
42. (New, SG No. 1/2014, effective 3.01.2014) "Rare disease"means a disease with a prevalence of not more than 5 in 10,000 of the population of the European Union.
43. (New, SG No. 58/2019) "Tobacco products" are the products within the meaning of Item 4 of § 1 of the supplementary provisions of the Tobacco, Tobacco Products and Related Products Act.
44. (New, SG No. 58/2019) "Products related to tobacco products" are the products within the meaning of Item 8 of § 1 of the supplementary provisions of the Tobacco, Tobacco Products and Related Products Act.
45. (New, SG No. 44/2020, effective 14.05.2020) An "emergency epidemic situation referred to in Article 63(1)" is in place in the event of a disaster caused by an infectious disease and resulting in the epidemic spread of said disease, which constitutes an immediate threat to the life and health of the public, where preventing and overcoming said disaster requires going above and beyond the general measures taken to protect the life and health of the public.
46. (New, SG No. 44/2020, effective 14.05.2020) "Isolation" means the separation of patients having an infectious disease referred to in Article 61(1) or (3) and carriers from the rest of the public with the aim of preventing the spread of the infectious disease in question.
47. (New, SG No. 44/2020, effective 14.05.2020) "Quarantine" means the separation of persons who have had contact with patients having an infectious disease referred to in Article 61(1) or (3) and persons arriving on the territory of Bulgaria from another country from the rest of the public with the aim of preventing the spread of the infectious disease in question.
48. (New, SG No. 8/2023) "Delay in the medical expert examination" shall be the failure to establish the type and extent of disability of children up to the age of 16 years and of persons eligible for length of service and old age pension pursuant to Article 68 of the Social Insurance Code; the extent of long-term limited capability for work of persons of working age, as well as to confirm occupational disease, within three months of the submission of the required application statement for re-assessment.

§ 1a. (New, SG No. 42/2010, effective 2.06.2010, amended, SG No. 80/2023) "Public places" within the meaning of Articles 54a, 56 and 56a (2) and (3) are all places which are publicly accessible and/or intended for public use, regardless of the property title or the right to access, including:
(a) the facilities under § 1(9)(b), (d), (e), (g), (j), (k), (n), (o), and (s);
(b) pharmacies, drugstores and opticians' shops;
(c) trade facilities within the meaning of § 1(41) of the Additional Provisions of the Value Added Tax Act;
(d) (amended, SG No. 30/2013, effective 26.03.2013) accommodation facilities, catering and entertainment facilities, catering facilities adjacent to tourist huts within the meaning of Article 3, Paragraph 2, items 1, 2 and 3 of the Tourism Act;

(e) (amended, SG No. 80/2023) food manufacturing, processing and distribution facilities; catering and entertainment facilities, 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 facilities and other buildings where citizens are serviced or to which they have access;
(g) elevators and staircases of all kinds of buildings;
(h) means of public transport - trains; aircraft; ships; buses; trams; trolleybuses; underground trains; fixed route taxi minibuses; taxis and means of transport for special purposes (sanitary service vehicles);
(i) (new, SG No. 40/2012) playgrounds.

§ 1b. (New, SG No. 1/2014, effective 3.01.2014) This Act shall ensure the implementation of Regulation (EC) No. 1223/2009 of the European Parliament and of the Council on Cosmetic Products.

§ 1c. (New, SG No. 1/2014, effective 3.01.2014) This Act shall introduce the requirements of Directive 2011/24/EU 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).

TRANSITIONAL AND FINAL PROVISIONS

§ 2. (1) The persons authorised to practise the medical profession under the repealed Public Health Act are legally competent medical specialists within the meaning of Article 184.
(2) (Repealed, SG No. 98/2010, effective 1.01.2011).

§ 2a. (New, SG No. 76/2005) (1) The persons who have acquired the educational qualification degree "Master" for the profession "Dentistry" have the rights of the persons who have acquired the educational qualification degree "Master" in "Dental Medicine".
(2) The Health Minister issues a document with which it certifies the rights of the persons under Paragraph (1).

§ 2b. (New, SG No. 59/2007) (1) The persons who have rights under § 32, Paragraphs (2) and (3) of the Transitional and Final Provisions of the Act to Amend and Supplement the Higher Education Act (promulgated, SG No. 41/2007) shall enjoy the rights of persons who have acquired a bachelor's degree under Article 42, Paragraph (1), Item 1(b) of the Higher Education Act to practice the profession provided that they have practised it for at least three years in succession during the past 5 years in the case of nurses, or for at least two years in succession during the past 5 years in the case of midwives.
(2) The persons who do not meet the experience requirements of Paragraph (1) shall enjoy the rights of persons who have acquired a bachelor's degree under Article 42, Paragraph (1), Item 1(b) of the Higher Education Act to practice the profession after they gain the required experience.

§ 2c. (New, SG No. 98/2010, effective 1.01.2011) (1) Paramedics who hold rights under § 32(2) and (3) of the Additional and Final Provisions of the Act Amending and Supplementing the Higher Education Act (SG No. 41 of 2007) shall enjoy the rights of medical assistants holding a Bachelor's Degree under Article 42(1)(1)(b) of the Higher Education Act in respect of the pursuit of the profession, provided that said paramedics have practiced a medical profession for at least two of the past 10 years.
(2) (Amended, SG No. 91/2018) Paramedics who hold rights under § 3 of the Additional and Final Provisions of the Professional Organisations of Medical Nurses, Midwives and Associated Medical Specialists, Dental Technicians and Assistant Pharmacists Guild Act shall enjoy the rights of medical assistants holding a Bachelor's Degree under Article 42(1)(1)(b) of the Higher Education Act in respect of the pursuit of the profession, provided that said paramedics have practiced a medical profession for at least three of the past 10 years.

§ 2d. (New, SG No. 102/2018, effective 1.01.2019) The time during which postgraduates have received training for acquiring a specialty based on an agreement for training for acquiring a specialty concluded in accordance with the procedure of the repealed Ordinance No 34 of 2006 on acquiring specialities in the health care system (promulgated, SG No. 7/2007; amended, SG No. 89/2007, No. 55/2008, Nos 12 and 72 of 2010, Nos 58 and 60 of 2011, No 50/2012, Nos 24 and 73 of 2013; amended with Ruling No 15612 of 26.11.2013 of the SAC of the Republic of Bulgaria – SG No. 59/2014, repealed, SG No. 7/2015) and have been insured in accordance with the procedure established by the repealed Article 4(1)(9) of the Social Insurance Code shall count as contributory service.

§ 3. The persons who were given a deadline for the degree of long-term limited capability for work as of 31 December 2004 shall be considered to have an established extent of long-term limited capability for work for life upon becoming 65 years of age.

§ 4. (1) Within one month of the effective date of this Act, the Council of Ministers shall re-organise the existing district healthcare centres into regional healthcare centres and the existing inspectorates for hygiene and epidemiology into regional inspectorates for public health protection and control.
(2) Within one month of the effective date of the ordinance under Paragraph (1), the Minister of Health shall issue Regulations on the Structure and Activities of Regional Healthcare Centres and Regulations on the Structure and Activities of Regional Inspectorates for Public Health Protection and Control.
(3) The persons exercising the state sanitary control at the inspectorates for hygiene and epidemiology as of the effective date of this Act, shall have the rights laid down in § 3 of the Transitional and Final Provisions of the Civil Servants Act.
(4) Regional inspectorates for health protection and control may conclude contracts with the NHIF until 31 December 2005.

§ 5. This Act shall repeal the Public Health Act (promulgated, SG No. 88/1973; amended, SG No. 92/1973; amended, SG Nos. 63/1976, 28/1983, 66/1985, 27/1986, 89/1988, 87 and 99/1989, 15/1991; amended, SG No. 24/1991; amended, SG Nos. 64/1993, 31/1994, 36/1995, 12, 87 and 124/1997, 21, 70, 71 and 93/1998, 30, 62, 67, 90 and 113/1999, 10 and 36/2000, 63/2002, 83 and 102/2003.

§ 6. In Article 52, Paragraph (2) of the Carriage by Road Act (promulgated, SG No. 82/1999; amended, SG Nos. 11 and 45/2002 and 99/2003), the word "sanitary" shall be replaced by the words "state health control authorities".

§ 7. The Safe Use of Nuclear Energy Act (promulgated, SG No. 63/2002; amended, SG No. 120/2002) shall be amended as follows:
1. In Article 15:
(a) In Paragraph (3), Item 6 is repealed;
(b) In Paragraph (4), Item 8 is repealed.
2. Article 18, Item 3 of Paragraph (1), is amended as follows:
"3. under Article 15, Items 2 to 5 of Paragraph (3) - within one month".
3. In Article 29:
(a) the existing text shall become Paragraph (1);
(b) Paragraph 2 shall be created:
"(2) No fee shall be payable for the issuance of an authorization to import or export sources of ionizing radiation or parts thereof."
4. In Article 31:
(a) there shall be inserted the following new Paragraph (2):
"(2) The initial licensing fee for the issuance of a license to use radioactive substances and other sources of ionizing radiation for medical purposes and the annual licensing fees shall be equal to 50 percent of the fees set out in Article 28 (1)."

(b) what was previously Paragraph (2) shall become Paragraph (3).
5. Article 57, (1) is repealed;
6. In Article 58:
(a) in Paragraph (1), Item 5 shall be repealed;
(b) In Paragraph (3), the words "of three" shall be inserted after the words "for a term";
7. Article 59 is amended as follows:
"Article 59. Permits for import of radioactive sources of ionizing radiation shall be issued if:
1. the intended holder of the said permit holds the requisite licence or permit entitling the said person to use and/or to store any such sources;
2. their carriage by a person licensed or authorized to perform carriage under this Act is ensured."
8. In Article 60:
(a) in Paragraph (2), the words "and/or national consultants for radiotherapy, nuclear medicine and radiology" are deleted;
(b) a new Paragraph (3) is created:
"(3) The official coordination under Paragraph (2) shall be carried out with the obligation that the sources of ionizing radiation may be used for medical purposes";
9. Article 61 is repealed;
10. In Article 62, the words "or the holder of an authorization" are inserted after the words "the licensee".

§ 8. In Article 47, (1) of the Higher Education Act (promulgated, SG No. 112/1995; amended, SG Nos. 28/1996, 56/1997; amended, SG No. 57/1997; amended, SG Nos. 58/1997, 60 and 113/1999, 54/2000, 22/2001, 40 and 53/2002, 48/2004) the words "the national centres for public health affairs" shall be inserted after the words "agrarian sciences".

§ 9. The Water Act (promulgated, SG No. 67/1999; amended, SG Nos. 81/2000, 34, 41 and 108/2001, 47, 74 and 91/2002, 42, 69, 84 and 107/2003, 6/2004) shall be amended as follows:
1. In Article 42, second sentence, the word "sanitary" is replaced by the words "for hygiene and epidemiology";
2. In Article 47 (2), the words "public health facilities" are replaced by the words "medical treatment facilities for hospital in-patient health care";
3. In Article 48, Item 7 of Paragraph (1), the word "sanitary" is replaced by the words "for hygiene and epidemiology";
4. In Item 1(f) of Article 151, the words "public health facilities" are replaced by the words "medical treatment facilities for in-patient health care".

§ 10. Everywhere in the Civil Registration Act (promulgated, SG No. 67/1999; amended, SG Nos. 28 and 37/2001, 54/2002, 63/2003), the words "healthcare facility", "The healthcare facility" and "specialised healthcare facilities" shall be replaced by the words "medical facility", "the medical facility" and "medical treatment facilities" respectively.

§ 11. The Civil Aviation Act (promulgated, SG No. 94/1972; amended, SG Nos. 30/1990, 16/1997, 85/1998, 12/2000, 34 and 111/2001, 52/2004) shall be amended as follows:
1. In Article 71 (1)(a), the words "healthcare facility" are replaced by the words "medical facility";
2. In Article 85 (2), the word "sanitary" is replaced by the word "healthcare".

§ 12. In Article 40 (1) of the Value Added Tax Act (promulgated, SG No. 153/1998; amended, SG No. 1/1999; amended, SG Nos. 44, 62, 64, 103 and 111/1999, 63, 78 and 102/2000, 109/2001, 28, 45 and 117/2002, 37, 42, 86 and 109/2003, 53/2004), the words "healthcare facilities under the Public Health Act" shall be replaced by the words "national centres for public health affairs" and the words "medical specialists under the Public Health Act" shall be replaced by the words "medical specialists under the Health Act".

§ 13. In Article 123, Item 2(d) of Paragraph (1), of the Road Traffic Act (promulgated, SG No. 20/1999; amended, SG Nos. 1/2000, 43, 45 and 76/2002, 16 and 22/2003, 6/2004), the words "healthcare facility" are replaced by the words "medical facility".

§ 14. In Article 83 (4) of the Rail Transport Act (promulgated, SG No. 97/2000; amended, SG Nos. 47 and 96/2002), the word "sanitary" shall be replaced by the words "state health control authorities".

§ 15. In Item 8 of Article 32, of the Child Protection Act (promulgated, SG No. 48/2000; amended, SG Nos. 75 and 120/2002, 36 and 63/2003), the words "of diseases under Arts. 36 and 36a of the Public Health Act" shall be replaced by the words "of AIDS and diseases under Article 61, (1) and Article 146, Items 1 and 2 of Paragraph (1), of the Health Act".

§ 16. In Article 37, Item 2 of Paragraph (2), of the Replacement of Military Obligations by an Alternative Service Act (promulgated, SG No. 131/1998; amended, SG Nos. 69/1999, 49/2000, 50/2003), the words "state sanitary control authorities" shall be replaced by the words "state health control authorities".

§ 17. The Health Insurance Act (promulgated, SG No. 70/1998; amended, SG Nos. 93 and 153/1998, 62, 65, 67, 69, 110 and 113/1999, 1, 31 and 64/2000, 41/2001, 1, 54, 74, 107, 112, 119 and 120/2002, 8, 50, 107 and 114/2003, 28, 38 and 49/2004) shall be amended as follows:
1. In Article 49, the words "state sanitary control" are replaced by the words "state health control";
2. In Article 58, the words "and healthcare facilities under the Public Health Act" shall be replaced by the words "national centres for public health affairs under the Health Act".

§ 18. The Health and Safety at Work Act (promulgated, SG No. 124/1997; amended, SG Nos. 86/1999, 64 and 92/2000, 25 and 111/2001, 18 and 114/2003) shall be amended as follows:
1. In Article 25, a new Paragraph (6) is inserted as follows:
"(6) The activities of labour medicine services shall be subject to accreditation under the terms and conditions set out for accreditation of medical treatment facilities under the Medical Treatment Facilities Act.";
2. In Article 37 (6), the word "sanitary" is replaced by the word "healthcare".

§ 19. In Article 9 of the Implementation of Penal Sanctions Act (promulgated, SG No. 30/1969; amended and supplemented, SG Nos. 34/1974, 84/1977, 36/1979, 28/1982, 27 and 89/1986, 26/1988, 21/1990, 109/1993, 50/1995, 12 and 13/1997, 73 and 153/1998, 49/2000, 62 and 120/2002, 61/2004), the words "sanitary requirements" shall be replaced by the words "healthcare requirements".

§ 20. The Blood, Blood Donation, and Blood Transfusion Act (promulgated, SG No. 102/2003) shall be amended as follows:
1. Article 34a shall be created:
"Article 34a. (1) All medical treatment facilities for in-patient health care and dispensaries with beds may take blood for autohaemotransfusion, while observing the requirements under Article 12 (2), where there exist no medical counter-indications thereof and upon receipt of an informed consent in writing.
(2) In the case of young persons, the informed consent in writing shall be obtained from the young person’s legitimate representative or guardian."
2. A new § 13 is inserted in the Additional Provision as follows:
"13. "Autohaemotransfusion" is the method, whereby the patient is transfused blood taken from the patient in advance."

§ 21. Everywhere in the Human Medicinal Drugs and Pharmacies Act (promulgated, SG No. 36/1995; SG No. 61/1996 - Judgement No. 10/1996 of the Constitutional Court; amended, SG Nos. 38/1998, 30/1999, 10/2000; SG No. 37/2000 - Judgement No. 3/2000 of the Constitutional Court; amended, SG No. 59/2000; SG No. 78/2000 - Judgement No. 7/2000 of the Constitutional

Court; amended, SG Nos. 41/2001, 107 and 120/2002; amended, SG No. 2/2003; Amended Nos. 56, 71 and 112/2003), the words "the Chief State Sanitary Inspector" shall be replaced by the words "the Chief State Health Inspector" and the words "inspectorates for hygiene and epidemiology" shall be replaced by the words "the regional inspectorate for public health protection and control" and "regional inspectorates for public health protection and control" respectively.

§ 22. The Medical Treatment Facilities Act (promulgated, SG No. 62/1999; amended, SG Nos. 88 and 113/1999; amended, SG No. 114/1999; amended, SG Nos. 36, 65 and 108/2000; SG No. 51/2001 - Judgement No. 11/2001 of the Constitutional Court; amended, SG Nos. 28 and 62/2002, 83, 102 and 114/2003) shall be amended as follows:

1. In Article 86:

(a) there shall be inserted the following new Paragraph (2):

"(2) Medical treatment facilities other than those under Paragraph (1) shall be subject to voluntary accreditation for assessment of their base capacity to train students, postgraduates and medical doctors for the purposes of the continuous medical education";

b) what was previously Paragraph (2) shall become Paragraph (3).

2. Article 91 is amended as follows:

"Article 91. Medical treatment facilities for out-patient care may offer practical training of postgraduates in the specialties laid down in the ordinance under Article 181 of the Health Act and training for the purposes of the continuous medical education."

3. Article 115 is amended as follows:

(a) in Paragraph (1), the words "from BGN 100 to BGN 300" are replaced by the words "from BGN 1000 to BGN 3000";

(b) a new Paragraph (2) shall be created:

"(2) Whoever provides out-patient medical care in violation of Article 39 shall be sanctioned by a fine from BGN 2,000 to BGN 5,000 and, in the case of recurring violation, with withdrawal of the right to practice the profession from three months to one year";

(c) the current Paragraph (2) becomes Paragraph (3) and there the words "from BGN 200 to BGN 500" are replaced by the words "from BGN 2000 to BGN 5000";

4. In Article 116:

(a) in Paragraph (1), the words "from BGN 100 to BGN 500" are replaced by the words "from BGN 1,000 to BGN 5,000";

(b) in Paragraph (2), the words "from BGN 750 to BGN 2,000" are replaced by the words "from BGN 8,000 to BGN 20,000";

5. Everywhere in the Act, the words "district healthcare centre", "the district healthcare centre" and "district healthcare centres" are replaced by the words "regional healthcare centre", "the regional healthcare centre" and "regional healthcare centres" respectively, while the words "inspectorate for hygiene and epidemiology" shall be replaced by the words "the regional inspectorate for public health protection and control".

§ 23. In Article 6, (1) of the Local Taxes and Fees Act (promulgated, SG No. 117/1997; amended, SG Nos. 71, 83, 105 and 153/1998, 103/1999, 34 and 102/2000, 109/2001, 28, 45, 56 and 119/2002, 84 and 112/2003, 6, 18 and 36/2004), the words "kitchens for children" shall be inserted after the word "crèches".

§ 24. Paragraph 3 of Article 82 of the Ministry of the Interior Act (promulgated, SG No. 122/1997; SG No. 29/1998 - Judgement No. 3/1998 of the Constitutional Court; amended, SG Nos. 70, 73 and 153/1998, 30 and 110/1999, 1 and 29/2000, 28/2001, 45 and 119/2002, 17, 26, 95, 103, 112 and 114/2003, 15/2004) shall be amended as follows:

"(3) Sobering facilities shall be established by the Ministry of Interior in coordination with local governments."

§ 25. The Maritime Space, Inland Waterways and Ports of the Republic of Bulgaria Act (promulgated, SG No. 12/2000; amended, SG Nos. 111/2001, 24/2004) shall be amended as follows:
1. In Article 23 (1), the word "sanitary" is replaced by the word "healthcare".
2. In Article 38 and Item 2 of Article 66, the words "sanitary provisions" are replaced by the words "healthcare requirements".

§ 26. In Article 19, Item 1 of Paragraph (2) of the Personal Income Tax Act (promulgated, SG No. 118/1997, SG No. 35/1998 - Judgement No. 6/1998 of the Constitutional Court; amended, SG Nos. 71 and 153/1998, 50, 103 and 111/1999, 105/2000, 110/2001, 40, 45, 61 and 118/2002, 42, 67, 95 and 112/2003, 36, 37 and 53/2004), the words "and health" shall be deleted.

§ 27. In Article 95 of the Waste Management Act (promulgated, SG No. 86/2003), the words "the director of the inspectorate for hygiene and epidemiology" is replaced by the words "the director of the regional inspectorate for public health care and control" and the word "sanitary" is replaced by the word "healthcare".

§ 28. In the Environmental Protection Act (promulgated, SG No. 91/2002; amended, SG No. 98/2002; amended, SG No. 86/2003), in Chapter Three after Article 59 a new Section VIII shall be inserted under the title Protection of the Environment Against Asbestos Pollution with Article 59a as follows:
"Section VIII. Protection of the Environment Against Asbestos Pollution
Article 59a. (1) The Minister of the Environment and Water, in consultation with the Minister of Health, shall issue an ordinance to establish:
1. the requirements and measures for the prevention and reduction of air and water pollution by asbestos;
2. the methods and procedures for detection of asbestos in dust emissions;
3. the methods and procedures for determination of the concentration of suspended solids in asbestos-containing wastewater;
4. the cases where exemptions from the requirements and measures referred to in Item 1 are admissible.
(2) The Minister of the Environment and Water may authorise the use of methods and procedures other than those under Paragraph (1) provided that they yield equivalent data and results."

§ 29. In Article 200k of the Judicial System Act (promulgated, SG No. 59/1994; SG No. 78/1994 - Judgement No. 8/1994 of the Constitutional Court; SG No. 87/1994 - Judgement No. 9/1994 of the Constitutional Court; SG No. 93/1995 - Judgement No. 17/1995 of the Constitutional Court; amended, SG No. 64/1996, SG No. 96/1996 - Judgement No. 19/1996 of the Constitutional Court; amended, SG Nos. 104 and 110 of 1996, SG Nos. 58, 122 and 124 of 1997, SG Nos. 11 and 133 of 1998, SG No. 6/1999 - Judgement No. 1/1999 of the Constitutional Court; amended, SG No. 34, 38 and 84 of 2000, SG No. 25/2001, SG No. 74/2002, SG No. 110/2002 - Judgement No. 11/2002 of the Constitutional Court, SG No. 118/2002 - Judgement No. 13/2002 of the Constitutional Court; amended, SG Nos. 61 and 112 of 2003, SG Nos. 29 and 36 of 2004), a new Paragraph (3) shall be inserted as follows:
"(3) The ordinance under Paragraph (2) shall establish also the terms and conditions for calculating and paying the costs of medical treatment facilities in the preparation of forensic medical expert reports."

§ 30. The Doctors and Dentists Professional Organisations Act (promulgated, SG No. 83/1998) shall be amended as follows:
1. In Article 4, the words "Articles 88 and 93 of the Public Health Act" are replaced by the words "Chapter Seven, Section II of the Health Act";
2. In Item 4 of Article 5, the words "together with the National Health Insurance Fund" are deleted;
3. Item 9 of Article 9, is repealed;

4. In Article 32 (3):
(a) Item 2 shall be amended to read as follows:
"2. a certificate of legal competence under the Health Act;";
(b) Item 6 is amended to read as follows:
"6. for foreign nationals - a long-term stay and work permit and a certificate of legal competence under the Health Act.";
5. In Article 33 (1), the words "Articles 88 and 93 of the Public Health Act" are replaced by the words "Chapter Seven, Section II of the Health Act";
6. A new § 6a is inserted in the Transitional and Final Provisions:
"§ 6a. The Bulgarian Medical Association and the Bulgarian Dental Association shall draft and adopt Rules for Good Medical Practice and submit them for approval to the Minister of Health before 1 July 2005."

§ 31. In Article 4 (4) of the Gambling Act (promulgated, SG No. 51/1999; amended, SG Nos. 103/1999, 53/2000, 1, 102 and 110/2001, 75/2002, 31/2003), a comma and the word "healthcare" shall be inserted after the word "educational".

§ 32. Everywhere in the Foodstuffs Act (promulgated, SG No. 90/1999; amended, SG No. 102/2003), the words "state sanitary control" shall be replaced by the words "state health control", the words "the Public Health Act" shall be replaced by the words "the Health Act" and the words "the Chief State Sanitary Inspector" shall be replaced by the words "the Chief State Health Inspector".

§ 33. In Article 24, (1), item 8 of the Foreigners in the Republic of Bulgaria Act (promulgated, SG No. 153/1998; amended, SG Nos. 70/1999, 42 and 112/2001, 45 and 54/2002, 37 and 103/2003, 37/2004), the words "healthcare facility" are replaced by the words "medical facility";

§ 34. Article 30, Paragraph (2) of the Tobacco and Tobacco Products Act (promulgated, SG No. 101/1993; amended, SG Nos. 19/1994, 110/1996, 153/1998, 113/1999, 33 and 102/2000, 110/2001, 20/2003, 57/2004) shall be amended as follows:
1. Item 1 shall be amended as follows:
"1. within the territory of crèches and kindergartens, schools, school boarding houses, medical and healthcare facilities;";
2. Item 5 is amended as follows:
"5. which do not meet healthcare requirements;";
3. In item 11, the words "at outlets licensed for duty-free trade" are deleted;
4. A new item 16 is inserted as follows:
"16. at sports and public events organised for children and pupils."

§ 35. In the Social Insurance Code (promulgated, SG No. 110/1999; SG No. 55/2000 - Judgement No. 5/2000 of the Constitutional Court; amended, SG Nos. 64/2000, 1, 35 and 41/2001, 1, 10, 45, 74, 112, 119 and 120/2002, 8, 42, 67, 95, 112 and 114/2003, 12, 38, 52 and 53/2004), Articles 14, 15, 16 and 17 shall be repealed.

§ 36. The Protection against Discrimination Act (promulgated, SG No. 86/2003) shall be amended as follows:
1. In Article 4 (1), the words "human genome" are inserted after the words "ethnic origin";
2. A new item 14 is inserted in § 1 of the Additional Provision:
"14. "Human genome" is the sum total of all genes in a single (diploid) set of chromosomes of an individual."

§ 37. The Personal Data Protection Act (promulgated, SG No. 1/2002) shall be amended as follows:
1. In Article 2 (1), the words "as well as the human genome data" shall be inserted at the end;
2. A new item 10 is inserted in § 1 of the Additional Provision:

"10. "Human genome" is the sum total of all genes in a single (diploid) set of chromosomes of an individual."

§ 38. The Council of Ministers shall adopt and the Minister of Health shall issue the secondary legislation on the implementation of this Act within a year of its effective date.

§ 39. Pending the entry into force of the secondary legislation under § 38, the existing secondary legislation on the implementation of the repealed Public Health Act shall apply, insofar as they do not contravene this Act.

§ 40. The implementation of this Act is hereby assigned to the Minister of Health.

§ 41. This Act shall enter into force on 1 January 2005, except for Article 53, (3) which shall enter into force on 1 January 2006.

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This Act was adopted by the 39th National Assembly on 29 July 2004 and the official seal of the National Assembly was affixed thereto.

TRANSITIONAL AND FINAL PROVISIONS
to the Act to Amend the Doctors and Dentists
Professional Organisations Act
(SG No. 76/2005, effective 1.01.2007)

§ 3. In the Health Act (promulgated, SG No. 70/2004, supplemented, SG No. 46/2005) the following amendments shall be made:

.....

2. Everywhere in the law the words "dental", "medical and dental, dental, medical and dental, dental, dentist, dentist, dentistry, dentists, dentistry" and "Union of dentists in Bulgaria "are replaced with" dental "," medical and dental, dental, medical and dental, dental, dental medicine, doctor of dental medicine, dental medicine, dental medicine, dental medicine "and" the Bulgarian Dental Association.

.....

TRANSITIONAL AND FINAL PROVISIONS
to the Act Amending and Supplementing the Health Act
(SG No. 85/2005, effective 25.10.2005,
amended, SG No. 59/2007, effective 26.05.2007)

§ 17. (1) The higher schools shall provide the training and the acquisition of "bachelor" educational and qualification degree in specialties from the "Health Care" vocational sector under the procedure of the Higher Education Act by the beginning of the 2006/2007 academic year.
(2) The persons who have begun their training in the specialties of "medical nurse" and "midwife" from the "Health Care" vocational sector of the "specialist" educational and qualification degree and by September 1, 2006 have not completed their education, shall continue their education at a department or branch of a higher school in the next academic year in the respective specialty from the "Health Care" vocational sector for the acquisition of a "bachelor" education and qualification degree without previously sitting for admission exams.
(3) (Repealed, SG No. 59/2007).
(4) The persons who have begun their "specialist" educational and qualification training as "remedial gymnast", "medical lab expert", "x-ray lab expert", "sanitary inspector" and "masseur" of the "Public Health" vocational section, as "dental mechanic" of the "Dentistry" vocational section and as "assistant pharmacist" of the "Pharmacology" vocational section, shall continue their training in the same specialties for acquiring the same educational degree in the "Health Care" vocational section.

.....

§ 22. This Act shall enter into force on the date of its promulgation in the State Gazette except for § 2 and § 18, Item 1 regarding deletion of the text "or "specialist" which shall enter into force on 1 September 2006.

TRANSITIONAL AND FINAL PROVISIONS
to the Administrative Procedure Code
(SG No. 30/2006, effective 12.07.2006)

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§ 61. The Health Act (promulgated in the State Gazette No. 70 of 2004; amended in No. 46 of 2005, Nos. 76, 85, 88, 94 and 103 of 2005, No. 18 of 2006) shall be amended as follows:

.....

2. the text "the Administrative Procedure Act" and the text "the Supreme Administrative Court Act" are replaced passim by "the Administrative Procedure Code".

.....

§ 142. This Code shall enter into force three months after the promulgation thereof in the State Gazette with the exception of:

1. Title Three, Item 1 of § 2 and Item 2 of § 2 herein (in respect of the repeal of Chapter Three, Section II "Appeal Before the Court"), Items 1 and 2 of § 9, Items 1 and 2 of § 11, § 15, Items 1 and 2 of § 44, Item 1 of § 51, Item 1 of § 53, Item 1 of § 61, Item 3 of § 66, Items 1 to 3 of § 76, § 78, § 79, Item 1 of § 83, Items 1 and 2 of § 84, Items 1 to 4 of § 89, Item 1 of § 101, Item 1 of § 102, § 107, Items 1 and 2 of § 117, § 125, Items 1 and 2 of § 128, Item 2 of § 132 and Item 1 of § 136, as well as § 34, Item 2 of § 35, Item 2 of § 43, Item 1 of § 62, Items 2 and 4 of § 66, Item 2 of § 97, and Item 1 of § 125 herein (in respect of the replacement of the word "district" by "administrative" and the replacement of the text "the Sofia City Court" by "the Sofia City Administrative Court"), which shall enter into force as from 1 March 2007;

.....

FINAL PROVISIONS
to the Act Amending and Supplementing the Health Act
(SG No. 59/2006, effective 1.01.2007)

.....

§ 21. This Act shall become effective on January 1, 2007, with the exception of § 4, 5 and 14 which shall become effective on the day of their promulgation in the State Gazette.

(*) ACT to Amend and Supplement to the Commercial Register Act
(SG No. 80/2006, effective 3.10.2006)

§ 1. In § 56 of the Transitional and Final Provisions the words "1 October 2006" shall be replaced by "1 July 2007".

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TRANSITIONAL AND FINAL PROVISIONS
to the Act Amending and Supplementing the Health Act
(SG No. 81/2006)

§ 5. (1) Handicraft enterprises providing services in the field of optics and optometry in operation by the date this Act becomes effective may continue to operate if they register under the procedure of Article 26b herein with the respective RHC within six months.

(2) Within six months after this Act becomes effective the owners of handicraft enterprises or the heirs, or the legal successors, providing services in the field of optics and optometry, as well as the apprentices, journeymen and masters, shall submit an application to the respective crafts chamber for the deletion thereof from the respective registers referred to in Articles 21, 48, 54 and 63 of the Skilled Crafts Act.

(3) In the cases referred to in Paragraph (2) the regional crafts chambers shall expunge the registration of the respective persons within 14 days following the filing of the application and shall issue a certificate for deletion of journeymen and masters on the basis of which they may enjoy the rights referred to in Article 26a.

§ 6. (1) The persons with acquired professional qualification in Optometry shall enjoy the rights referred to in Article 26a (2) and (3) and may undertake measures for the correction of sight.
(2) Persons with acquired professional qualification as "assistant pharmacist and dispensing optician" shall enjoy the rights referred to in Article 26a (2) and (3), and the persons with acquired professional qualification in Optics, Optomechanical and Optoelectronic Devices shall enjoy the rights referred to in Article 26a (3).

TRANSITIONAL AND FINAL PROVISIONS
to the Act Amending and Supplementing the Health Insurance Act
(SG No. 95/2006, effective 24.11.2006)

§ 13. Not later than the 1st day of December 2006:
1. the Minister of Health shall issue the ordinance referred to in Article 80a (3) herein;
2. the Director of the National Health Insurance Fund shall endorse a standard form of a European health insurance card.

TRANSITIONAL AND FINAL PROVISIONS
to the Medicinal Products in Human Medicine Act
(SG No. 31/2007, effective 13.04.2007)

.....
§ 19. (1) Within a period of three months of the coming of this Act into force:
1. The Council of Ministers shall amend and supplement the Organic Rules of the Bulgarian Drugs Agency, bringing it in line with this Act;
2. The Minister of Health shall issue the Ordinance under Article 82, Paragraph 3.
(2) Within a period of up to six months of the coming of this Act into force, the Council of Ministers shall adopt and the Minister of Health shall issue the other legislative instruments for the enforcement of this Act.

§ 20. After expiry of the first two years of the term of office of the members of Commissions under Articles 103, 107, 259 and 261, half of the members whose term of office will terminate shall be drawn by lot.

§ 21. Within one year after the entry into force of this Act the Bulgarian Drug Agency shall take the necessary steps to accredit its laboratory for control over medicinal products and active substances by the European Directorate for the Quality of Medicines and Healthcare.
.....

§ 36. Until the coming into force of the instruments under § 19, legal instruments issued for the enforcement of the repealed Human Medicinal Drugs and Pharmacies Act shall apply, insofar as they do not stand in contradiction hereto.

§ 37. This Act shall become effective on the day of its publication in the State Gazette with the exception of § 22, which shall enter into force one year after the entry of this Act into force.

TRANSITIONAL AND FINAL PROVISIONS
to the Medical Devices Act
(SG No. 46/2007, effective 12.06.2007)

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§ 15. In the Health Act (promulgated, SG No. 70/2004; amended, SG Nos. 46, 76, 85, 88, 94 and 103 of 2005, SG Nos. 18, 30, 34, 59, 71, 75, 81, 95 and 102 of 2006, SG No. 31/2007) in item 9,

lettera "h" of § 1 of the supplementary provision the word "medicines" shall be replaced by "medicinal products; and medical devices".

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TRANSITIONAL AND FINAL PROVISIONS
to the Act to Amend and Supplement the
Republic of Bulgaria Defence and Armed Forces Act
(SG No. 46/2007, effective 1.01.2008)

.....

§ 69. Item 3 of Article 200, Paragraph 2 of the Health Act (promulgated in the State Gazette No. 70 of 2004; amended in Nos. 46, 76, 85, 88, 94 and 103 of 2005, Nos. 18, 30, 34, 59, 71, 75, 81, 95 and 102 of 2006, Nos. 31 and 41 of 2007) shall be repealed.

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(*) ACT to Amend and Supplement to the Commercial Register Act
(SG No. 53/2007, effective 30.06.2007)

§ 1. In § 56 of the Transitional and Final Provisions, the words "1 July 2007" shall be replaced by "1 January 2008."

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TRANSITIONAL AND FINAL PROVISIONS
to the Recognition of Professional Qualifications Act
(SG No. 13/2008, effective 8.02.2008)

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§ 15. (1) The secondary legislation and the other acts relating to the implementation of this Act shall be issued with a month of its entry into force.

(2) Pending the entry into force of the acts under Paragraph 1, the existing implementation acts under the provisions repealed in accordance with § 6, 7, 8, 9, 10, 11 and 12 shall apply, unless they contravene this Act.

.....

TRANSITIONAL AND FINAL PROVISIONS
to the Act to Amend and Supplement the Health Act
(SG No. 41/2009, effective 2.06.2009, amended, SG No. 98/2010,
effective 14.12.2010, supplemented, SG No. 40/2012)

§ 65. (Effective 1.07.2009 – SG No. 41/2009) Any procedures initiated before TMEP and NMEP for the assessment of children up to the age of 16 years and persons eligible for length of service and old age pension pursuant to Article 68 of the Social Insurance Code which have not been completed before 1 July 2009 shall continue to be examined under the procedure existing hitherto but not later than 31 December 2009.

§ 65a. (New, SG No. 40/2012) In the events where there are no Paediatric Medical Expert Panels open, the expertise of the type and extent of disability of children up to the age of 16 years under requests for assessment (re-assessment) submitted after 1 July 2009 shall be carried out by TMEP with the participation of paediatricians.

§ 66. (Effective 1.07.2009 – SG No. 41/2009) Persons whose extent of long-term limited capability for work has been determined for life under the procedure existing hitherto and persons whose long-term limited capability for work has been determined for life pursuant to § 3 shall be deemed to have their type and extent of disability determined for life.

§ 67. Schools, kindergartens and specialised institutions providing social services referred to in Article 26 (1), Item 3 where no healthcare offices have been established as of the entry into force of this Act shall establish healthcare offices not later than 1 July 2011.

§ 68. (1) Within two months of entry into force of this Act the Council of Ministers shall adopt the rules of procedure for the Medical Audit Executive Agency.
(2) Within six months of entry into force of this Act the secondary legislation which ensues from it shall be adopted.

.....

§ 80. (1) (Effective 1.07.2009 - SG No. 41/2009) (1) Evidence of formal qualifications in a regulated profession recognised by the relevant competent authority prior to the entry into force of this Act shall give access to and the right to pursue the relevant regulated profession in the Republic of Bulgaria under the same terms and conditions as applicable to evidence recognised in accordance with the procedure provided for in the Recognition of Professional Qualifications Act.
(2) (Amended, SG No. 98/2010, effective 14.12.2010) The evidence of professional qualifications issued in the former Union of Soviet Socialist Republics to persons who started practicing the relevant regulated profession in the Republic of Bulgaria on the grounds of Article 1(3) of the repealed Ordinance No. 29 of 1975 concerning the recognition of evidence of education issued by schools of foreign countries (promulgated, SG No. 2 of 1975; repealed, SG No. 20 of 1996) and had practiced it prior to the entry into force of this Act, shall confer the rights under Paragraph 1.

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§ 94. (1) Medical practitioners who have not obtained a specialism in general medicine within the timeline set forth in § 6 (1), Item 1 of the Transitional and Final Provisions of the Medical Treatment Facilities Act shall have the right to continue working as individual or group practice for primary medical care for a period of five years following the entry into force of this Act.
(2) Once the timeline set forth in Paragraph (1) has expired, the registration of medical practitioners with the relevant Regional Healthcare Centre shall be deleted where they have failed to obtain a specialism in general medicine.

§ 95. Medical practitioners who have registered a medical facility under Article 13 (1) or Article 14 (1) of the Medical Treatment Facilities Act prior to the entry into force of this Act and who hold a recognised specialism in internal diseases, paediatrics or emergency medicine may carry out activities as individual or group practice for primary medical care without obtaining a specialism in general medicine.

§ 96. This Act shall enter on the date of the promulgation thereof in the State Gazette, with the exception of:
1. Paragraphs 3, 5, 6 and 9, which shall enter into force as of 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 as of 1 July 2009;
3. Paragraph 21, which shall enter into force as of 1 June 2010.

FINAL PROVISIONS
to the Act Amending and Supplementing
Vocational Education and Training Act
(SG No. 74/2009, effective 15.09.2009)

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§ 29. In the Health Act (promulgated, SG No. 70/2004, amended, SG No. 46, 76, 85, 88, 94 and 103/2005, SG No. 18, 30, 34, 59, 71, 75, 80, 81, 95 and 102/2006, SG No. 31, 41, 46, 53, 59, 82 and 95/2007, SG No. 13, 102 and 110/2008, SG No. 36 and 41/2009) everywhere in the text the words "the Minister of Education and Science" and "the Ministry of Education and Science" shall be replaced by "the Minister of Education, Youth and Science" and "the Ministry of Education, Youth and Science", respectively.

.....

ACT to Amend and Supplement the Health Insurance Act
(SG No. 101/2009, effective 18.12.2009)

.....

§ 72. The Health Act (promulgated, SG No. 70/2004; amended, SG Nos 46, 76, 85, 88, 94 and 103 of 2005, Nos 18, 30, 34, 59, 71, 75, 80, 81, 95 and 102 of 2006, Nos 31, 41, 46, 53, 59, 82 and 95 2007, Nos 13, 102 and 110 of 2008, and Nos 36, 41, 74, 82, 93 and 99 of 2009) shall be amended and supplemented as follows:

.....

8. "Medical Inspectorate" shall be replaced by "medical audit" throughout the Act.

.....

§ 76. (1) The Council of Ministers shall adopt before 31.01.2010 the Statute on the Organisation under Article 116a, Paragraph 4 of the Health Act.

(2) The Economic Analysis and Forecasts Agency shall develop before 1.11.2010 the volumes, prices and costing and paying methodologies for medical care under Article 55, Paragraph 2, item 2.

§ 77. This Act shall enter on the date of the promulgation thereof in the State Gazette, with the exception of:

1. Paragraphs 4, 5, 10 (as to Article 15, Paragraph 1, item 2), 26, 27 (item 1, letter "b", item 2, 4, 5 and 6), 28, 29, 30, 33, 34, 35, 37, 38, 39, 40, 41, 42, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 56, 57, 58, 59, 60, 61, 62, 64 (item 2), 69, 72 (item 3, 4, 5, 6, 7 and 8), 73 and 75, which shall enter into force on 1.01.2010.
2. Paragraphs 25 and 27, item 1, letter "a" which shall enter into force on 2.01.2010.
3. Paragraph 63 which shall enter into force on 1.02.2010.
4. Paragraph 36 (as regards Article 55c) which shall enter into force on 1.01.2011.
5. Paragraphs 31 and 43 (item 1) which shall enter into force on 1.01.2012.
6. Paragraph 27, item 3 which shall enter into force on 1.01.2013.
7. Paragraph 29(1)(b) which shall enter into force as of 1 January 2011.

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FINAL PROVISIONS
to the Act Amending and Supplementing the Health Act
(SG No. 42/2010, effective 2.06.2010)

§ 6. Within three months upon the entry into force of this Act, the Council of Ministers shall adopt the ordinance referred to in Article 56a(3).

TRANSITIONAL AND FINAL PROVISIONS
to the Act Amending and Supplementing the Health Act
(SG No. 98/2010, effective 1.01.2011)

§ 93. (1) By decree, the Council of Ministers shall transform the regional health centres and regional inspectorates for public health protection and control existing at the time of entry into force of this Act into regional health inspectorates. The transformation shall be completed within one month following the date of entry into force of the Act.

(2) Within the time limit under Paragraph 1, the Minister of Health shall issue the regulations under Article 10(3).

(3) The operations, assets, records, rights and obligations of the transformed regional health centres and regional inspectorates for public health protection and control shall be taken over by the respective regional health inspectorates.

(4) Employment relationships with the directors of the regional health centres and regional inspectorates for public health protection and control shall be terminated as per the procedure laid down in Article 328(1)(2) of the Labour Code within one month following the adoption of the decree and regulations under Paragraph 1 and 2.

(5) Within three months upon expiration of the time limit under Paragraph 4, the Minister of Health shall announce and hold the competitions for the post of RHI director as per the procedure laid down in Article 9(2).
(6) Until a competition under Paragraph 5 is held, the post of RHI director shall be assigned on the grounds of an employment relationship pursuant to Article 68(1)(4) of the Labour Code.
(7) Service and employment relationships of the staff of the transformed regional health centres and regional inspectorates for public health protection and control shall be settled as per the procedure laid down in Article 87a of the Civil Servants Act and Article 123 of the Labour Code, in line with the number of staff and the structure of the regional health inspectorates determined in the decree and regulations under Paragraph 1 and 2.
(8) Until transformed within the time limit under Paragraph 1, the regional health centres and regional inspectorates for public health protection and control existing at the time of entry into force of this Act shall continue to carry out their incumbent operations under the Health Act and other statutory instruments.

.....

§ 121. This Act shall take effect on 1 January 2011, except for:
1. § 1, 16, 20, 29, 30, 32, 33, 34, 35, 42, 44, § 56, Items 1 and 2, § 65, 68, 70, 76, 80, 81, 90, 92, 96, § 102, Items 3, 4, 5, 7 and 8, § 105, Items 1, 3 and 5, § 107, Items 1, 2, 3, 4, 6(a), 7, 10, 11, 13 and 15(a), § 109, 110, 112, 113, § 115, Item 5, § 116, Items 4 and 6, § 117, Items 5 and 7 and § 118, Item 1, which shall take effect on the day of the Act's promulgation in the State Gazette;
2. paragraph 102, items 1, 2 and 6, which shall enter into force on 1 March 2011;
3. paragraphs 22, item 1 (concerning article 36, paragraph 1, second sentence), § 37, § 48, item 2, § 51 and § 59, which shall enter into force on 1 July 2011;
4. § 107, Item 15(b), which shall take effect on 30 September 2011.

TRANSITIONAL AND FINAL PROVISIONS
to the Act to Amend and Supplement the Social Insurance Code
(SG No. 100/2010, effective 1.01.2011)

§ 51. In the Health Act (promulgated, SG No. 70/2004; amended, No. 46, 76, 85, 88, 94 and 103/2005, No. 18, 30, 34, 59, 71, 75, 80, 81, 95 and 102/2006, No. 31, 41, 46, 53, 59, 82 and 95/2007, No. 13, 102 and 110/2008, No. 36, 41, 74, 82, 93, 99 and 101/2009 and No. 41, 42, 50, 59 and 62/2010) in Article 105, paragraph 3 shall be repealed.
.....

§ 65. This Act shall take effect on 1 January 2011, with the exception of § 32, 33, 36 and 51, which shall enter into force from 1 January 2012.

TRANSITIONAL AND FINAL PROVISIONS
Act to Amend and Supplement the Civil Servants Act
(SG No. 38/2012, effective 1.07.2012)

.....

§ 84. (Effective 18.05.2012 - SG No. 38/2012) Within one month after the promulgation of this Act in the State Gazette:
1. the Council of Ministers shall bring the Classifier of Positions in the Administration into conformity with this Act;
2. the competent authorities shall bring the organic acts of the respective administration into conformity with this Act.

§ 85. (1) The legal relationships with the persons of the administrations under the Radio and Television Act, the Independent Financial Audit Act, the Electronic Communications Act, the Financial Supervision Commission Act, the Access to and Disclosure of the Documents and Announcing the Affiliation of Bulgarian Citizens with the State Security Service and the Intelligence Services of the Bulgarian Popular Army Act, the Criminal Assets Forfeiture Act, the

Conflict of Interest Prevention and Ascertainment Act, the Social Insurance Code, the Health Insurance Act, the Agricultural Producers Support Act and the Roads Act shall be settled under the terms established by § 36 of the Transitional and Final Provisions of the Act to Amend and Supplement the Civil Servants Act (SG No. 24/2006).
(2) The act on appointment of the civil servant shall:
1. award the lowest rank designated in the Classifier of Positions in the Administration for occupation of the position, unless the servant holds a higher rank;
2. fix an individual monthly basic salary.
(3) The additional resources required for social and health insurance contributions of the persons referred to in Paragraph (2) shall be provided within the limits of the expenditures on salaries, remunerations and compulsory social and health insurance contributions under the budgets of the spending units concerned.
(4) The Council of Ministers shall effect the requisite modifications under the off-budget account of State Fund Agriculture arising from this Act.
(5) The governing bodies of the National Social Security Institute and of the National Health Insurance Fund shall effect the requisite modifications under the respective budgets arising from this Act.
(6) Any unused leaves under the employment relationships shall be retained and shall not be compensated by cash compensations.

§ 86. (1) Within one month after the entry into force of this Act, the individual monthly basic salary of the servant shall be fixed in such a way that the said salary, net of the tax due and the compulsory social and health insurance contributions for the account of the insured person, if they were due, would not be lower than the gross monthly salary received theretofore, net of the compulsory social and health insurance contributions for the account of the insured person, if they were due, and the tax due.
(2) The gross salary referred to in Paragraph (1) shall include:
1. the monthly basic salary or the monthly basic remuneration;
2. supplementary remunerations which are paid constantly together with the monthly basic salary or monthly basic remuneration due and which are contingent solely on the time worked.

§ 87. This Act shall enter into force as from the 1st day of July 2012 with the exception of § 84 herein, which shall enter into force as from the day of promulgation of the Act in the State Gazette.

TRANSITIONAL AND FINAL PROVISIONS
to the Act to Amend and Supplement the Health Act
(SG No. 40/2012)

§ 18. Within 7 days of the entry of this Act into force the medical institutions, to which TMEP have been opened assessing (reassessing) children up to the age of 16 years, shall be obliged to ensure the participation of a paediatrician in the TMEP.

.....

§ 22. The provisions of § 1, 2, 3, 12, 13, 14, 15 and 21 shall become effective from 1 June 2012.

TRANSITIONAL AND FINAL PROVISIONS
to the 2013 National Health Insurance Fund Budget Act
(SG No. 101/2012, effective 1.01.2013)

§ 1. The over-implementation of the health insurance revenues specified in Article 1, Paragraph 1, line 1 shall be allocated for health insurance payments in accordance with a procedure determined by the NHIF Supervisory Board.

§ 2. The Ministry of Health shall monthly, by the end of the current month, provide transfers to the budget of the NHIF under Article 1, Paragraph 1, line 5 in the amount of the liability to the medical institutions undertaken during the month for the obstetrics care provided by them as per Article 82, Paragraph 1, Item 2 of the Health Act and for financing the expenses on vaccines under national programmes for prevention of cervical cancer for a certain population as per Article 82, Paragraph 2, Item 3 of the Health Act. The funds shall be accounted for as per Article 1, Paragraph 2, line 1.1.3.5.3 and line 1.1.3.7.1 of the NHIF budget.

§ 3. From the executive budget via the budget of the Ministry of Health earmarked subsidies may be received into the budget of the NHIF according to Article 23, Paragraph 1, Item 11 of the Health Insurance Act, outside those under Article 1, Paragraph 1, for the execution of obligations stemming from the application of the rules for coordination of the social security systems and intended for in-kind compensations outside the medical care under Article 45 of the Health Insurance Act. The amounts under Article 1, Paragraph 2, lines 1, 1.1.3, 1.1.3.8 and 1.1.3.8.1 shall be increased with the expenditure incurred for these compensations.

§ 4. The funds under hospital care contracts, executed between spenders of budgetary appropriations and the NHIF, shall be accounted for as transfers under Article 1, Paragraph 2, line 2.

§ 5. The amounts due in accordance with the requirements of Article 24, Item 6 of the Health Insurance Act from the NHIF budget to the National Revenue Agency budget shall be calculated, planned and distributed at the end of each calendar month in the amount of 0.2 percent of the health insurance contributions raised during the preceding month. The funds shall be accounted for as transfers between budget accounts in Article 1, Paragraph 2, line 2.

§ 6. The NHIF Supervisory Board shall have the right to make internal offset changes in the allocations between the components of the total expenditure and transfers, specified in Article 1, Paragraph 2, where the changes must be within the budget approved, except for the personnel costs under Article 1, Paragraph 2, Item 1.1.1.

§ 7. On the grounds of Article 26, Paragraph 2 of the Health Insurance Act the NHIF Supervisory Board shall have the right to spend funds from the reserve, including for unforeseen and emergency expenditures under Article 1, Paragraph 2, line 1.3.

§ 8. The NHIF Supervisory Board may make a decision that the revenues from the sale of tangible long-term assets are to be used for the acquisition of such assets above the approved expenditure according to Article 1, Paragraph 2, line 1.2.

§ 9. (1) The Supervisory Board, upon a proposal by the NHIF Manager, shall approve the required changes in individual items of expenditure, incurred by the NHIF and financed with funds from transfers from the Ministry of Health, not envisaged in this Act, without disrupting the balance of the NHIF budget.
(2) The transfers from the Ministry of Health, referred to in Paragraph 1, shall be for individuals with no health insurance and shall include:
1. activities related to the ambulatory follow-up of patients with mental disorders;
2. activities related to the ambulatory follow-up of patients with skin and venereal diseases;
3. intensive care;
4. one preventive check-up and tests for all women with no health insurance, regardless of the type of delivery, in accordance with Article 82, Paragraph 1, Item 2 of the Health Act.
(3) The amount of the transfers referred to in Paragraph 2 shall be determined and provided by the Ministry of Health for individuals with no health insurance under conditions and in accordance with a procedure, defined by the Minister of Health and the NHIF Manager.

§ 10. The vaccines for mandatory immunisations and re-immunisations, provided by the Ministry of Health in 2012, shall be financed in 2013 by the Ministry of Health under the existing procedure until they start being provided by the NHIF, but not later than 1 April 2013.

§ 11. (1) The medical institutions, which have been subsidised in 2012 by the Ministry of Health in accordance with the procedure of the Methodology for Subsidising Medical Institutions in 2012, shall be subsidised in 2013 by the Ministry of Health under the existing procedure, if by 31 December 2012 they have provided reports and statements in accordance with the concluded contracts for the activities, which shall be transferred for financing to the NHIF in 2013.
(2) The activities referred to in Paragraph 1 shall be paid for by the Ministry of Health after the final amount of the subsidy for the fourth quarter of 2012 is determined.

§ 12. (1) In 2013 the funds for medicines under Article 4, Item 1 of the War Veterans Act and Article 15, Paragraphs 1 and 2 of the War Invalids And Victims Act shall be covered from the executive budget and shall be paid by the Social Assistance Agency through the NHIF.
(2) The Social Assistance Agency shall transfer to the NHIF the funds required for payment of the amounts, requested by pharmacies, which have concluded contracts with the NHIF, for medicines provided to war veterans, disabled veterans and people injured in wars.
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FINAL PROVISIONS
to the Act to Amend the Youth Act
(SG No. 68/2013, effective 2.08.2013)
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§ 32. The following amendments shall be introduced in Health Act (promulgated, SG No. 70/2004, amended, SG No. 46, 76, 85, 88, 94 and 103/2005, SG No. 18, 30, 34, 59, 71, 75, 80, 81, 95 and 102/2006, SG No. 31, 41, 46, 53, 59, 82 and 95/2007, SG No. 13, 102 and 110/2008, SG No. 36, 41, 74, 82, 93, 99 and 101/2009, SG No. 41, 42, 50, 59, 62, 98 and 100/2010, SG No. 8, 9, 45 and 60/2011, SG No. 38, 40, 54, 60, 82, 101 and 102/2012, SG No. 15 and 30/2013):
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2. In the rest of the text of the Act the words "Minister of Education, Youth and Science" and "Ministry of Education, Youth and Science" shall be replaced by "Minister of Education and Science" and "The Ministry of Education and Science" respectively.
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FINAL PROVISIONS
to the Act to Amend and Supplement the Veterinary Practices Act
(SG No. 99/2013)

.....
§ 14. Within 6 months of this Act’s entry into force the Minister of Health and the Minister of Agriculture and Food shall adopt the ordinance under Article 62, Paragraph 2 of the Health Act.
.....

TRANSITIONAL AND FINAL PROVISIONS
to the 2014 National Health Insurance Fund Budget Act
(SG No. 106/2013, effective 1.01.2014)

.....
§ 17. In Health Act (promulgated, SG No. 70/2004, amended, SG No. 46, 76, 85, 88, 94 and 103/2005, SG No. 18, 30, 34, 59, 71, 75, 80, 81, 95 and 102/2006, SG No. 31, 41, 46, 53, 59, 82 and 95/2007, SG No. 13, 102 and 110/2008, SG No. 36, 41, 74, 82, 93, 99 and 101/2009, SG No. 41, 42, 50, 59, 62, 98 and 100/2010, SG No. 8, 9, 45 and 60/2011, SG No. 38, 40, 54, 60, 82, 101 and 102/2012, SG No. 15, 30, 66, 68 and 99/2013) in Article 82 The following amendments and additions:

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§ 19. This Act shall enter into force on January 1, 2014, except § 15, which shall enter into force on the date of promulgation of the law in the "State Gazette".

TRANSITIONAL AND FINAL PROVISIONS
to the 2014 Public Social Insurance Budget Act
(SG No. 106/2013, effective 1.01.2014)

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§ 6. (Effective 1.12.2014 - SG No. 106/2013) In the Health Act (promulgated, SG No. 70/2004, amended, SG No. 46, 76, 85, 88, 94 and 103/2005, SG No. 18, 30, 34, 59, 71, 75, 80, 81, 95 and 102/2006, SG No. 31, 41, 46, 53, 59, 82 and 95/2007, SG No. 13, 102 and 110/2008, SG No. 36, 41, 74, 82, 93, 99 and 101/2009, SG No. 41, 42, 50, 59, 62, 98, 100/2010, SG No. 8, 9, 45 and 60/2011, SG No. 38, 40, 54, 60, 82, 101 and 102/2012, SG No. 15, 30, 66, 68 and 99/2013) creates Article 103a:

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§ 9. This Act shall enter into force on 1 January 2014 with the exception of § 6, which comes into force on December 1, 2014.

TRANSITIONAL AND FINAL PROVISIONS
to the Act Amending and Supplementing the Health Act
(SG No. 1/2014, effective 3.01.2014)

§ 13. The existing health certificates for the export of products and goods of importance to human health issued prior to the entry into force of this Act shall be valid within the time limits specified therein.

§ 14. The applications for issuance of certificates for the export of products and goods of importance to human health filed prior to the entry into force of this Act shall be examined under the previous terms and conditions, whereby the details under Article 37(2)(4) shall be attached to the applications for the issuance of export certificates for cosmetic products.

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§ 17. Within one month from coming into force of this act the Minister of Health issues the orders under:
1. Article 37, Paragraph 8, Article 52 and Article 114a, Paragraph 2;
2. Article 80e, Paragraph 4 of the Health Insurance Act.

§ 18. Within one month from coming into force of this act the Minister of Health puts into conformity with it the Ordinance referred to in Article 221, Paragraph 1 of the Medicinal Products in Human Medicine Act.

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TRANSITIONAL AND FINAL PROVISIONS
to the 2017 National Health Insurance Fund Budget Act
(SG No. 98/2016, effective 1.01.2017)

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§ 12. The Health Act (promulgated, SG No. 70/2004; amended, SG Nos. 46, 76, 85, 88, 94 and 103 of 2005, SG Nos. 18, 30, 34, 59, 71, 75, 80, 81, 95 and 102 of 2006, SG Nos. 31, 41, 46, 53, 59, 82 and 95/2007, SG Nos. 13, 102 and 110 of 2008, SG Nos. 36, 41, 74, 82, 93, 99 and 101 of 2009, SG Nos. 41, 42, 50, 59, 62, 98 and 100 of 2010, SG Nos. 8, 9, 45 and 60 of 2011, SG Nos. 38, 40, 54, 60, 82, 101 and 102 of 2012, SG Nos. 15, 30, 66, 68, 99, 104 and 106 of 2013, SG Nos. 1, 98 and 107 of 2014, SG Nos. 9, 72, 80 and 102 of 2015, SG Nos. 17 and 27 of 2016) is amended and supplemented as follows:

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§ 14. The Act shall enter into force on 1 January 2017.

TRANSITIONAL AND FINAL PROVISIONS
of the 2017 Public Social Insurance Budget Act
(SG No. 98/2016, effective 1.01.2017)

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§ 10. In the Health Act (promulgated, SG No. 70 of 2004; amended and supplemented, SG Nos. 46, 76, 85, 88, 94 and 103 of 2005, SG Nos. 18, 30, 34, 59, 71, 75, 80, 81, 95 and 102 of 2006, SG Nos. 31, 41, 46, 59, 82 and 95 of 2007, SG Nos. 13, 102 and 110 of 2008, SG Nos. 36, 41, 74, 82, 93, 99 and 101 of 2009, SG Nos. 41, 42, 50, 59, 62, 98 and 100 of 2010, SG Nos. 8, 9, 45 and 60 of 2011, SG Nos. 38, 40, 54, 60, 82, 101 and 102 of 2012, SG Nos SG Nos. 15, 30, 66, 68, 99, 104 and 106 of 2013, SG Nos. 1, 98 and 107 of 2014, SG Nos. 9, 72, 80 and 102 of 2015 and SG Nos. 17 and 27 of 2016), paragraph 11 is created in Article 112:

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§ 12. The Act shall enter into force on 1 January 2017, except for:
1. Paragraph 5, which enters into force as of 9 August 2016;
2. Paragraph 3, Items 13 – 15, and § 8, which shall enter into force as of 1 June 2017;
3. Paragraph 3, Item 2 which shall enter into force as of 1 January 2018.

TRANSITIONAL AND FINAL PROVISIONS
to the Act to Amend and Supplement the Health Act
(SG No. 18/2018, effective 27.02.2018)

§ 2. (1) Within two months of the entry of this Act into force, the specialised NMEP divisions shall be brought in line with the requirements of this Act.
(2) Any procedures for carrying out medical expert activities by the specialised NMEP divisions, which have begun and have not been completed before the entry of this Act into force, shall be completed according to the procedure established by this Act.

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§ 4. Within two months of the entry of this Act into force, the secondary legislation shall be brought in line with the requirements of this Act.

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TRANSITIONAL AND FINAL PROVISIONS
to the 2019 National Health Insurance Fund Budget Act
(SG No. 102/2018, effective 1.01.2019)

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§ 43. This Act shall enter into force on 1 January 2019, with the exception of:

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2. paragraph 28, items 6 – 12 and items 14 – 19, § 35, item 3, with the exception of Article 7a, paragraph 4 and Article 7c, paragraph 4, items 5 and 6, items 8 – 22 and items 36 – 40, § 41, items 2 – 8, item 9, letters "a" and "c" and item 10, which shall become effective on 1 April 2019;

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TRANSITIONAL AND FINAL PROVISIONS
to the Social Services Act
(SG No. 24/2019, effective 1.07.2020 - amended, SG No. 101/2019;
amended, SG No. 110/2020, effective 31.12.2020, SG No. 8/2022,
effective 1.01.2022, SG No. 104/2022, effective 1.01.2023)

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§ 41. (1) The provisions of the Health Act, the Health Insurance Act, the Employment Promotion Act, the Legal Aid Act, the Local Taxes and Fees Act, the Veterinary Practices Act, the Bulgarian Personal Documents Act, the Civil Registration Act and the Environmental Protection Act that are

applicable to social and integrated health and social services for residential care, to the heads of such services and to the persons who use such services shall apply mutatis mutandis to the homes for children deprived of parental care, their heads and the persons placed in them until said homes are closed down.
(2) The provisions of the Health Act, the Health Insurance Act, the Legal Aid Act, the Employment Promotion Act, the Veterinary Practices Act, the Environmental Protection Act, the War Invalids and Victims Act, the Persons with Disabilities Act and the Local Taxes and Fees Act that are applicable to the social and integrated health and social services for residential care and to the persons who use such services shall apply mutatis mutandis to the homes for adults with mental retardation, homes for adults with mental disorders, homes for adults with physical disabilities, homes for adults with sensory disorders and homes for adults with dementia and to the persons placed in them until said homes are closed down.
(3) Until the homes for medical and social care for children are closed down, Article 124(2) of the Health Act shall apply to the children placed in said homes.
(4) Until the homes for children deprived of parental care and the homes for medical and social care for children are closed down, Article 8e(6) of the Family Allowances for Children Act, Article 22c(2)(3) and Article 22d(2)(3) of the Income Taxes on Natural Persons Act shall apply when children are placed in said homes.
(5) The provisions of the Income Taxes on Natural Persons Act and the Corporate Income Tax Act that are applicable to donations to the benefit of social and integrated health and social services for residential cate shall apply mutatis mutandis to the donations to homes for children deprived of parental care, homes for adults with mental retardation, homes for adults with mental disorders, homes for adults with physical disabilities, homes for adults with sensory disorders and homes for adults with dementia until said homes are closed down.

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§ 45. (Amended, SG No. 101/2019) This Act shall enter into force on 1 July 2020 with the exception of:
1. (amended, SG No. 110/2020, effective 31.12.2020, SG No. 8/2022, effective 1.01.2022, SG No. 104/2022, effective 1.01.2023) paragraph 6, subparagraph 5(a), paragraph 7, subparagraph 2(a) and (b), subparagraph 3, subparagraph 6(a), subparagraph 9 and subparagraph 10, paragraph 18(2) in the part concerning the "homes for medical and social care for children in accordance with the Medical Treatment Facilities Act" and paragraph 20, subparagraph 2 in the part concerning the deleting of the test "and the homes for medical and social care for children" and subparagraph 5(c), which shall enter into force on 31 December 2023;
2. paragraph 3(4)(f), (g) and (h) and paragraph 28, subparagraph 1(a) and subparagraphs 2 and 5, which shall enter into force on 1 January 2019;
3. Article 22(4), Article 40, Article 109(1), Article 124, Article 161(2), paragraphs 3(6), 30, 36, 37 and 43, which shall enter into force as from the day of promulgation of this Act in the State Gazette.
2. paragraph 3(4)(f), (g) and (h) and paragraph 28, subparagraph 1(a) and subparagraphs 2 and 5, which shall enter into force on 1 January 2019;
3. Article 22(4), Article 40, Article 109(1), Article 124, Article 161(2), paragraphs 3(6), 30, 36, 37 and 43, which shall enter into force as from the day of promulgation of this Act in the State Gazette.

FINAL PROVISIONS
to the Act Amending and Supplementing the Health Act
(SG No. 58/2019)

§ 7. Within 4 months of the entry of this Act into force the Minister of Health shall issue the ordinance referred to in Article 29(3).

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TRANSITIONAL AND FINAL PROVISIONS
to the Act on the Measures and Actions during

the State of Emergency Declared by a Resolution
of the National Assembly of 13 March 2020
(SG No. 28/2020, effective 13.03.2020)

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§ 52. This Act shall enter into force on the 13th day of March 2020 with the exception of Article 5, § 3, § 12, § 25 – 31, § 41, § 49 and § 51 which shall enter into force as from the day of the promulgation of this State Gazette and shall be applicable until the abrogation of the state of emergency.

TRANSITIONAL AND FINAL PROVISIONS
to the Act Amending and Supplementing the Health Act
(SG No. 44/2020, effective 14.05.2020)

§ 13. The periods suspended over the course of the state of emergency declared under the Act on the Measures and Actions during the State of Emergency Declared by a Resolution of the National Assembly of 13 March 2020 and suspended to overcome the relevant repercussions shall resume seven days after the promulgation of this Act in the State Gazette.

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§ 16. (1) The unpaid leave referred to in Article 160(1) of the Labour Code not exceeding 60 working days and used in 2020 shall be counted towards a worker's period of service.
(2) In 2020, the duration of a period of unpaid leave not exceeding 60 working days shall be counted towards a worker's period of service referred to in Article 9(2)(3) of the Social Insurance Code and relevant to their old-age pension rights.

§ 17. By 31 December 2020, acting on a proposal by the mayor of their respective municipality, the heads of social services performing activities delegated by the state and local-level activities shall be authorised to order staff members on their teams to perform activities within the framework of other social services on the territory of said municipality without requiring said staff members' consent.

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§ 19. (1) Over the course of the 2019 – 2020 school year, the national external assessment at the end of grades 4 and 9 referred to in Article 119(3) of the Pre-school and School Education Act to assess the level of competence attainment at these stages shall not be conducted.
(2) Following a dedicated decision by the Minister of Education and Science, the level of competence attainment of students who have finished their grade 4 or 9 studies relevant to their respective educational stages during the 2019 - 2020 school year may be assessed at the start of the 2020 – 2021 school year.
(3) The 2020 – 2021 school year admission of students in integrated schools shall proceed solely on the basis of the final grades in school subjects included in their certificates of completed first stage of secondary education.

§ 20. (1) Any and all medical establishments providing active treatment hospital care designated by an order of the Minister of Health for the purposes of conducting the treatment and monitoring of COVID-19 patients shall ensure that their officials conduct a monthly inspection of the state of energy facilities owned by them and meant to supply them with electricity, including electrical installations, backup power generators and facilities that automatically switch between sources of electricity and thus ensure the continuity of electricity supply.
(2) A statement of findings shall be drawn up, listing the results of the inspection referred to in Paragraph (1).
(3) Where cases of non-compliance with statutory requirements are detected, the persons referred to in Paragraph (1) shall take steps to eliminate said cases without delay with a view to ensuring the continuity of electricity supply.

(4) The persons referred to in Paragraph (1) shall notify the Ministry of Energy of the steps taken by them without delay following the inspections conducted.

§ 21. (1) To ensure energy security, the pricing/regulatory period relevant to electricity sector companies and ending on 30 June 2020 may be extended by two months as of the date on which the period is set to end at present.
(2) Where the period referred to in Paragraph (1) is extended, the Energy and Water Regulatory Commission shall issue its decisions on applications for the approval of prices submitted by energy companies prior to this Act's entry into force.

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§ 23. (1) For the duration of the 2020 summer tourist season, as of1 June 2020 the concession holder or lessee under an effective concession contract or lease contract, respectively, relevant to a beach along the sea coast shall offer beach amenities within the meaning of § 1(6), Annexes 1 and 2 of the Additional Provisions section of the Black Sea Coast Development Act (parasols and deckchairs), at a discount of not less than 50 % of the fees set for the 2019 season or of the maximum fees set out in their contract.
(2) By 25 May 2020, the concession holder or lessee respectively shall communicate the fees for beach amenities for the 2020 summer season to the Minister of Tourism set in compliance with Paragraph (1). By 30 May 2020, the Minister of Tourism shall inform the concession holder or, respectively, the lessee of the reduced concession fee or lease due determined for 2020 according to the methodology referred to in Paragraph (6), with said fee or lease corresponding to the reduction in beach amenities fees referred to in Paragraph (1). The concession holder shall pay their 2020 concession fee by 30 November 2020.
(3) In cases falling under Paragraph (2), the Council of Ministers may act on a proposal by the Minister of Tourism and reduce the amount of the 2020 concession fee due and the Minister of Tourism may issue an order to reduce the amount of 2020 lease. Where the fee or lease has already been paid in full or in part, the relevant reduction shall be deducted from the 2021 concession fee or lease respectively.
(4) In line with the decision or order referred to in Paragraph (3), the Minister of Tourism and the concession holder or lessee shall conclude and additional agreement, which shall become part of the concession contract or lease contract respectively.
(5) On a proposal by the concession holder or lessee, the concession or lease period respectively may be extended by not more than one year, regardless of whether the statutory maximum duration of the period under the relevant type of contact is exceeded. The concession grantor or lessor respectively is entitled to accept or refuse said proposal, offering reasons. The Minister of Tourism and the concession holder or lessee shall conclude and additional agreement to the concession contract or lease contract respectively.
(6) The reduction of the concession fee or lease due, which must correspond to the reduction in beach amenities fees, and the extension of the concession or lease contract period shall be set on the basis of a methodology that shall be proposed by the Minister of Tourism and approved by the Council of Ministers by 23 May 2020.
(7) Any person that fails to meet the requirement referred to in Paragraph (1) shall be imposed a pecuniary sanction to the amount of BGN 50,000 and, in the event of a repeat violation, a pecuniary sanction to the amount of BGN 100,000. A repeat violation shall constitute a violation that takes place within four months of the penalty order imposing a penalty for the same type of violation relevant to the same beach becoming effective.
(8) The establishment of violations shall be entered in statements drawn up by officials designated by the Minister of Tourism. Penalty orders shall be issued by the Minister of Tourism or officials authorised by them.

§ 24. (1) The concession holder under a concession contract relevant to a beach may propose the postponement, reduction or reallocation of some or all of its investments to be made in

2020 and 2021 under the concession contract or propose new investments. The concession grantor is entitled to accept or refuse the proposal, offering reasons.
(2) The contracts referred to in Paragraph (1) shall be amended by annexes, to be signed by the relevant parties by 31 December 2020, and following an adoption of a decision on the part of the concession grantor, except in the cases referred to in Article 8u(13) of the Black Sea Coast Development Act.

§ 25. (1) For the purposes of the 2020 summer season, additional retail areas, aside from the areas referred to in Article 10(7) of the Black Sea Coast Development Act, may be used on the territory of beaches along the sea coast in 2020, more specifically as part of the operation of establishments referred to in Article 10(4)(2)(b) of the same Act. Said retail areas shall not exceed 4 % of the territory of the beach.
(2) Any person that fails to meet the requirement referred to in Paragraph (1) shall be imposed a fine of between BGN 1,000 and 5,000 or a pecuniary sanction of between BGN 2,000 and 20,000. In the event of a repeat violation, the fine shall stand at between BGN 2,000 and 6,000 and the pecuniary sanction - between BGN 4,000 and 40,000. A repeat violation shall constitute a violation that takes place within four months of the penalty order imposing a penalty for the same type of violation relevant to the same beach becoming effective.
(3) The statements establishing violations referred to in Paragraph (1) shall be drawn up by officials designated by the Minister of Tourism. Penalty orders shall be issued by the Minister of Tourism or officials authorised by them.

§ 26. In 2020, the concession holder or lessee may designate areas on the territory referred to in Article 10(4)(1) of the Black Sea Coast Development Act to deter and control the entry of visitors in according to schemes approved by the Minister of Tourism.

§ 27. In 2020, the number of lifeguards stationed at each lifeguard tower located on the territory of a beach at which lifeguard presence is mandatory may be reduced to one.

§ 28. (1) The term of validity of certificates under the Tourism Act attesting to the category of Class A and B tourist accommodation, mass-catering and entertainment establishments (whether stand-alone or attached to tourist accommodations) tourist lodges, tourist training centres and tourist dormitories and mass-catering establishments attached to these, which expires after 1 September 2019, shall be extended until 31 December 2020.
(2) The term of validity of certificates attesting to the category of spa, medical spa, wellness and thalassotherapeutic centres relevant to establishments whose certificates under the Tourism Act expire after 1 September 2019 shall be extended until 31 December 2020.

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§ 34. (Effective 13.05.2020 - SG No. 44/2020) Any and all persons falling within the scope of Article 47(7) to (10) of the Excise Duties and Tax Warehouses Act shall ensure compliance of their operations with said Act and submit a notification on the items below to the Head of the Customs Agency within one month of the entry into force of this Act:
1. any variations to licences already issued for the removal of an oil product pipeline(s) from a tax warehouse structure, and issuance of a new, individual licence(s) for facilities already removed from a tax warehouse;
2. any variations to licences already issued whose scope covers production facilities for oil processing and their related oil pipeline or oil product pipeline, and issuance of a new, individual licence(s).
(2) The notification shall contain all information and documents necessary for the issuance of a licence for tax warehouse management under the Excise Duties and Tax Warehouses Act.
(3) Where ascertaining all facts and circumstances relevant to the issuance of a decision to vary an existing licence or the issuance of a new licence(s) for tax warehouse management is required, the person that submits the notification referred to in Paragraph (1) shall be entitled to apply for a one-month suspension of proceedings, offering reasons for said application. The application may be

submitted within 14 days of the notification referred to in Paragraph (1) being submitted or within the deadline for elimination of any irregularities found.
(4) The decision to vary the existing licence(s) and the new licence(s) issued following the submission of a notification under Paragraph 1(1) or (2) shall be returned at the same time.
(5) The securities relevant to the tax warehouse(s) referred to in the application under Paragraph (1) shall be presented prior to the issuance of the licence(s).
(6) The stocks of excisable goods found by customs authorities as at the date on which the documents referred to in Paragraph (4) are presented shall be entered in the stock records of the relevant tax warehouses and shall not be considered released for consumption. Electronic administrative documents shall be registered to that effect.
(7) Where a notification is not submitted within the deadline referred to in Paragraph (1), the licence falling within the scope of Article 47(7) to (10) of the Excise Duties and Tax Warehouses Act shall be terminated.
(8) Until the Head of the Customs Agency issues their decision on whether compliance with Article 47(7) to (10) of the Excise Duties and Tax Warehouses Act has been achieved, but not for longer than 30 November 2020, the persons that have submitted a notification referred to in Paragraph (1) shall continue to operate as licenced warehousekeepers.

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§ 36. Within six months of the state of emergency being lifted, the Employment Agency shall transfer compensation to the amount of BGN 290.00 to specific categories of persons subject to social insurance under the Social Insurance Code based on criteria and conditions set out in a dedicated act by the Council of Ministers. The amount cited shall be wired to the relevant insurer/self-employed person. Funding for this shall come from the European Structural and Investment Funds.

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§ 38. (1) Until the end of 2020, the Minister of Finance may authorise granting loans credited to the state budget and subject to repayment by the end of 2021. Said loans may be granted to municipalities in view of the implementation of anti-epidemic measures under Article 63 of the Health Act on their respective territories or in the event of temporary cash imbalances in a municipality’s budget resulting from a decrease in the collectability of real estate tax, vehicle tax and household waste charges as compared for 2019 figures covering the same period.
(2) Loans referred to in Paragraph (1) shall be granted following a reasoned application by the mayor of the relevant municipality and a decision by the relevant Municipal Council; Article 103(5) of the Public Finance Act and Articles 14 and 15 of the Municipal Debt Act shall not apply.
(3) The provisions of Articles 105 and 106 of the Public Finance Act shall not apply to loans referred to in Paragraph (1).

§ 39. The transfer for maintaining roads in winter and clearing snow off these made by 20 January 2020 and referred to in Article 53(4) of the 2020 State Budget of the Republic of Bulgaria Act may be used by municipalities for the purposes of implementing anti-epidemic measures under Article 63 of the Health Act on their respective territories.

§ 40. (1) In 2020, costs referred to in Article 62(3) of the Local Taxes and Fees Act may include costs incurred in the course of implementing measures under Article 63 of the Health Act in public areas in settlements and settlement-like localities on the territory of a municipality.
(2) The costs referred to in Paragraph (1) shall be covered by a redistribution of the municipal budget but shall not require amendments to the method of determining the amount of household waste charges or amendments to the charges themselves, as adopted by the Municipal Council.

§ 41. (1) Until 31 December 2020, up to 30 % of the funds accumulated according to the provisions of Article 60(2)(1) and (2) and Article 64(1) of the Waste Management Act may be expended to cover costs relevant to the implementation of measures referred to in Article 63(4) and (7) of the Health Act and related to meeting the requirements set out in the Waste Management Act.

(2) The funds referred to in Paragraph (1) shall be expended following a decision of the relevant Municipal Council endorsed by the Minister of the Environment and Water.
(3) The 2020 monthly contributions referred to in Article 60(2)(1) and (2) and Article 64(1) of the Waste Management Act for the period between 1 March 2020 and 30 November 2020 shall be made by 31 December 2020.
(4) For the period between 1 March 2020 and 31 December 2020, interests shall not accrue on the amounts due in monthly contributions referred to in Article 60(2)(1) and (2) and Article 64(1) of the Waste Management Act.

§ 42. In 2020, the ban on construction and installation works at national resorts along the Black Sea coast under Article 15 of the Black Sea Coast Development Act shall run between 15 June and 1 October.

§ 43. (1) Until 31 October 2020, working-age unemployed persons receiving monthly benefits under Article 12(1)(1) of the Social Assistance Act and not part of the employment schemes under Article 12b of said Act may conclude employment contracts for short-term seasonal labour in the agricultural sector with a term of not more than 120 days but this period of employment shall not be counted towards said persons' period of service.
(2) The employment contract referred to in Paragraph (1) shall provide for a full 8-hour working day, except where the parties to said contact have agreed to a 4- or 6-hour working day.
(3) The conclusion and termination of the employment contract referred to in Paragraph (1) shall be governed by the provisions of Article 62(3) and (4), Article 127(1)(4) and Article 128a(3) of the Labour Code.
(4) The employment contract referred to in Paragraph (1) shall contain details on the parties, the place of employment, the name of the relevant position, the dates and months in which work is to take place, working day duration, the start and end times of working hours and data entered ex officio by the Labour Inspectorate Directorate registering the relevant contract form.
(5) The employment contract referred to in Paragraph (1) shall be drawn up in line with a form approved by an order of the Minister of Labour and Social Policy and shall be published on the website on the General Labour Inspectorate Executive Agency.
(6) The employer, a farmer registered under the Agricultural Producers Support Act or a registered tobacco producer under the Tobacco, Tobacco Products and Related Products Act, may obtain registered forms of the employment contracts referred to in Paragraph (1).
(7) A registered farmer or tobacco producer may obtain forms of the employment contracts referred to in Paragraph (1) either in person or electronically from the relevant Labour Inspectorate Directorate.
(8) Remuneration shall be paid on the day on which the term of the employment contract referred to in Paragraph (1) expires. An acknowledgement of receipt of remuneration shall be signed to this effect and shall become an integral part of said contract.
(9) The social security and health insurance contributions of persons referred to in Paragraph (1) shall be made by insurers that have concluded a contract according to Paragraph (1) within the periods referred to in Article 7(1) of the Social Insurance Code and Article 40(1) of the Health Insurance Act.
(10) The persons referred to in Paragraph (1) shall remain entitled to monthly benefits under Article 12(1)(1) of the Social Assistance Act for the term of their contract referred to in Paragraph (1).
(11) Until 31 October 2020, the fundamental economic activity "Plant Production: Harvesting" shall be considered an activity within the meaning of § 1(5) of the Additional Provisions section of the Employment Promotion Act.

§ 44. This Act shall become effective on 14 May 2020, with the exception of § 33, 34 and 35, which shall become effective on the day of their promulgation in the State Gazette.

TRANSITIONAL AND FINAL PROVISIONS
to the 2021 National Health Insurance Fund Budget Act

(SG No. 103/2020, effective 1.01.2021)

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§ 24. This Act shall force as of 1 January 2021, except for § 17, 22 and 23, which shall enter into force as of the date of its publication in the State Gazette.

TRANSITIONAL AND FINAL PROVISIONS
to the Act to Amend and Supplement the Persons with Disabilities Act
(SG No. 105/2020, effective 1.01.2021, amended, SG No. 8/2022,
effective 1.01.2022, SG No. 18/2022, effective 1.04.2022)

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§ 25. (Effective 1.07.2022 – amended, SG No. 8/2022, effective 1.01.2022, SG No. 18/2022, effective 1.04.2022) Paragraph 2a is inserted in Article 108a of the Health Act (promulgated in SG No. 70/2004; amended, SG Nos 46, 76, 85, 88, 94 and 103 of 2005, SG Nos 18, 30, 34, 59, 71, 75, 80, 81, 95 and 102 of 2006, SG Nos 31, 41, 46, 53, 59, 82 and 95 of 2007, SG Nos 13, 102 and 110 of 2008, SG Nos 36, 41, 74, 82, 93, 99 and 101 of 2009, SG Nos 41, 42, 50, 59, 62, 98 and 100 of 2010, SG Nos 8, 9, 45 and 60 of 2011, SG Nos 38, 40, 54, 60, 82, 101 and 102 of 2012, SG Nos 15, 30, 66, 68, 99, 104 and 106 of 2013, SG Nos 1, 98 and 107 of 2014, SG Nos 9, 72, 80 and 102 of 2015, SG Nos 17, 27, 98 and 103 of 2016, SG Nos 58, 85 and 102 of 2017, SG Nos 18, 77, 91, 98 and 102 of 2018, SG Nos 24, 58 and 99 of 2019, and SG Nos 23, 28, 34, 44 and 67 of 2020):

.....

§ 26. (Amended, SG No. 8/2022, effective 1.01.2022, SG No. 18/2022, effective 1.04.2022) This Act shall enter into force as of 1 January 2021, except for § 1, 2, 7, 9, 10, 13 – 17 and 25, which shall enter into force as of 1 July 2022.

FINAL PROVISIONS
to the Act to Amend and Supplement the Health Act
(SG No. 105/2020, effective 11.12.2020)

.....

§ 9. The Act shall enter into force on the date of its publication in the State Gazette.

TRANSITIONAL AND FINAL PROVISIONS
Act to Amend and Supplement the Code of Civil Procedure
(SG No. 110/2020, effective 30.06.2021)

.....

§ 24. A third sentence is inserted in Article 158(5) of the Health Act (promulgated in SG No. 70/2004; amended, SG Nos 46, 76, 85, 88, 94 and 103 of 2005, SG Nos 18, 30, 34, 59, 71, 75, 80, 81, 95 and 102 of 2006, SG Nos 31, 41, 46, 53, 59, 82 and 95 of 2007, SG Nos 13, 102 and 110 of 2008, SG Nos 36, 41, 74, 82, 93, 99 and 101 of 2009, SG Nos 41, 42, 50, 59, 62, 98 and 100 of 2010, SG Nos 8, 9, 45 and 60 of 2011, SG Nos 38, 40, 54, 60, 82, 101 and 102 of 2012, SG Nos 15, 30, 66, 68, 99, 104 and 106 of 2013, SG Nos 1, 98 and 107 of 2014, SG Nos 9, 72, 80 and 102 of 2015, SG Nos 17, 27, 98 and 103 of 2016, SG Nos 58, 85 and 102 of 2017, SG Nos 18, 77, 91, 98 and 102 of 2018, SG Nos 24, 58, 99 and 101 of 2019, and SG Nos 23, 28, 34, 44, 67, 103 and 105 of 2020):

.....

§ 27. (Effective 31.12.2020 – SG No. 110/2020) The Social Services Act (promulgated in the SG No. 24 of 2019; amended, SG No. 101 of 2019, Judgement No. 9 of the Constitutional Court of 2020 – SG No. 65 of 2020; amended, SG No. 71 of 2020) shall be amended and supplemented in the Transitional and Final Provisions as follows:

.....

§ 28. This Act shall enter into force on 30 June 2021 with the exception of:
1. Paragraphs 9 and 25, which shall enter into force as of 30 July 2022;

2. Paragraphs 26 and 27, which shall enter into force on 31 December 2020.

TRANSITIONAL AND FINAL PROVISIONS
to the Act Amending and Supplementing the Health Insurance Act
(SG No. 21/2021, effective 12.03.2021)

§ 2. (1) As an exception in 2021 in case of declared state of emergency due to epidemic spread of infectious diseases under Article 61, Paragraph 1 or 3 of the Health Act or in case of declared emergency epidemic situation due to epidemic spread of a infectious disease under Article 61, Paragraph 1 of the Health Act, the mechanism under Article 45, Paragraph 31 shall not be applied to the medicinal products, obtained from human plasma or from human blood - immunoglobulins, included in the Positive Drug List under Article 262, Paragraph 6, Items 1 and 2 of the Medicinal Products in Human Medicine Act, paid by the NHIF:
1. fully or partially for home treatment on the territory of the country;
2. in the conditions of hospital medical care, outside the value of the medical services provided.
(2) The expenses of the NHIF for the medicinal products under Paragraph 1 above the target funds set in the 2021 National Health Insurance Fund Budget Act, taking into account the share of the reserve in a decision of the NHIF Supervisory Board under Article 15, Paragraph 1, Item 7, shall not be subject to reimbursement by the holders of marketing authorizations/their authorized representatives of the medicinal products for which the mechanism under Article 45, Paragraph 31 applies.
(3) The provisions of Paragraphs 1 and 2 shall apply until the cancelation of the state of emergency, respectively the emergency epidemic situation.
.....

TRANSITIONAL AND FINAL PROVISIONS
to the 2022 National Health Insurance Fund Budget Act
(SG No. 18/2022, effective 1.01.2022)

.....
§ 18. (Effective 4.03.2022 - SG No. 18/2022) In the Health Act (promulgated in SG No. 70/2004; amended, SG Nos 46, 76, 85, 88, 94 and 103 of 2005, SG Nos 18, 30, 34, 59, 71, 75, 80, 81, 95 and 102 of 2006, SG Nos 31, 41, 46, 53, 59, 82 and 95 of 2007, SG Nos 13, 102 and 110 of 2008, SG Nos 36, 41, 74, 82, 93, 99 and 101 of 2009, SG Nos 41, 42, 50, 59, 62, 98 and 100 of 2010, SG Nos 8, 9, 45 and 60 of 2011, SG Nos 38, 40, 54, 60, 82, 101 and 102 of 2012, SG Nos 15, 30, 66, 68, 99, 104 and 106 of 2013, SG Nos 1, 98 and 107 of 2014, SG Nos 9, 72, 80 and 102 of 2015, SG Nos 17, 27, 98 and 103 of 2016, SG Nos 58, 85 and 102 of 2017, SG Nos 18, 77, 91, 98 and 102 of 2018, SG Nos 24, 58, 99 and 101 of 2019, and SG Nos 23, 28, 34, 44, 67, 103, 105 and 110 of 2020, SG Nos 21 and 8 of 2022) a second sentence shall be created in Article 82 (6):
.....

§ 20. This Act shall become effective on 1 January 2022, with the exception of § 18 and 19 which shall become effective on the day of their promulgation in the State Gazette.

TRANSITIONAL AND FINAL PROVISIONS
to the 2022 State Budget of the Republic of Bulgaria Act
(SG No. 18/2022, effective 1.01.2022)

.....
§ 20. (Effective 1.04.2022 – SG No. 18/2022) In the Act to Amend and Supplement the Persons with Disabilities Act (promulgated, SG No. 105/2020, amended, SG No. 8/2022) the following amendments shall be made to the transitional and final provisions:
.....
5. In § 26 the words "1 April" are replaced with "1 July".
.....

§ 22. This Act shall enter into force on 1 January 2022, with the exception of:
1. paragraphs 6 and 20, which shall enter into force on 1 April 2022;
.....

FINAL PROVISIONS
to the Act Amending and Supplementing the Health Act
(SG No. 32/2022, effective 26.04.2022)

.....
§ 10. The Council of Ministers shall bring the National Plan for Preparedness in the Event of Pandemic, adopted by Council of Ministers Decision N0. 884/2020, in accordance with the requirements set out in this Act within one month of the entry of this Act into force.

§ 11. The Act shall come into force from the date of its promulgation in the State Gazette, with the exception of § 6 which shall come into force from 1 April 2022.

TRANSITIONAL AND FINAL PROVISIONS
to the Act Amending and Supplementing the Persons with Disabilities Act
(SG No. 8/2023)

.....
§ 5. Proceedings for the re-assessment of persons before the medical examination authorities that were initiated and were not concluded before the entry of this act into force, as well as the proceedings that were initiated and were not concluded until four months after its entry into force, shall be completed by applying Article 101b of the Health Act, regardless of the deadline for submission of an application statement by the persons or by persons authorised thereby, or by their legal representatives.

§ 6. The entitlements of and the support for the persons with an expired expert decision who have submitted an application statement for re-assessment until the entry of this act into force shall be reinstated ex-officio upon receipt of information from the regional health inspectorates when there is a delay within the meaning of § 1(48) of the supplementary provisions of the Health Act. The regional health inspectorates shall send information to the competent authorities specified in Article 101b(3) of the Health Act within fourteen days of the entry of this act into force.

§ 7. The information specified in Article 101b(3) of the Health Act shall also be sent through an information database under Article 108a(1) of the Health Act, and such an opportunity shall be created within three months of the entry of this act into force.