

LAW OF HEALTH

Prom. SG. 70/10 Aug 2004, amend. SG. 46/3 Jun 2005, amend. SG. 76/20 Sep 2005, amend. SG. 85/25 Oct 2005, amend. SG. 88/4 Nov 2005, amend. SG. 94/25 Nov 2005

In force from 1st of January 2005

Chapter one. NATIONAL SYSTEM OF HEALTH CARE

Section I. General Provisions

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

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

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

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

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

(3) The Council of Ministers, at a proposal of the Minister of Health shall adopt national health programmes.

(4) The National Health Strategy and the national health programmes shall be based on an assessment of the health status and health needs of the citizens, the health demographic tendencies and the resource capacity of the national system of health care.

(5) The national health programmes shall be financed by the republican budget as

differentiated expenses of the budget of the Ministry of Health and may be supported through other financial resources.

Art. 4. The national system of health care shall include the medical establishments under the Law for the medical establishments, the health establishments under this law and the Law for the medicines and pharmacies in the human medicine, as well as the state, municipal and public bodies and institutions for organisation, management and control of the activities related to preservation and strengthening of health.

Section II.

Bodies of management of the national system of health care

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

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

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

(3) The Minister of health shall approve the allocation of the subsidies of the republican budget for the activities - subject of this law, according to programmes, with exception of the activities under para 1, item 1 and 2.

(4) (amend., SG 88/05) The Minister of Health shall exercise methodological management and control of the medical activity of the medical establishments at the Council of Ministers, the Ministry of defence, the Ministry of Interior, the Ministry of Justice and the Ministry of Transport.

(5) The Minister of Health shall also exercise other legal capacities assigned to him by a law or by a normative act of the Council of Ministers.

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

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

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

comments on:

1. the priorities of the National Health Strategy;
2. ethical problems of the medicine and biomedicine;
3. draft laws and draft normative acts of the Council of Ministers in the sphere of health care and of the competence of the Minister of Health;
4. the report of the Minister of Health under art. 5, para 2;
5. the annual draft budget of the health care;
6. the scientific priorities in the sphere of medicine and stomatology;
7. the annual admission of students and specialists of professional sphere "health care" and the criteria for determining the educational centres for students and post-graduate studies under art. 91 and 92 of the Law for the medical establishments;
8. the kinds of specialities of professional sphere "health care".

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

Art. 7. (1) The state health policy on the territory of the region shall be implemented and organised by a regional health care centre (RHCC) and regional inspection for preservation and control of the public health (RIPCPh).

(2) For organising the health care in the municipalities the respective municipal council may establish a health care office within the municipal administration. The activity of the office shall be carried out under the methodological management of the regional health care centre.

Art. 8. (1) The regional health care centres are corporate bodies at budget support - secondary administrators of budget credits with the Minister of Health, with a seat in the settlement - administrative centre of the region.

(2) The regional health care centres shall be established, transformed and closed down by the Council of Ministers.

Art. 9. (1) The regional health care centre shall be managed and represented by a director who will occupy the position on the grounds of a competition announced by the Minister of Health.

(2) Director of RHCC may be a person having a three-year practice on the speciality "medicine" or "stomatology".

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

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

Art. 10. (1) The regional health care centres shall carry out activities of:

1. control over the registration and the health activity carried out by the medical establishments and health consulting rooms on the territory of the respective region;

2. control over the fulfilment of the medical standards approved by the order of art. 6, para 1 of the Law for the medical establishments and over the organisation of providing quality of the medical activity in the health and medical establishments;

3. introduction of information technologies in the sphere of health care;

4. gathering, registration, processing, storing, analysis and submitting of health information for the needs of the national system of health care;

5. planning, organising, management and control of the medical expertise on the territory of the respective sphere;

6. planning and organisation of the health care activities during calamities, accidents and catastrophes on the territory of the respective region;

7. inspections regarding complaints and signals of citizens related to the medical services;

8. coordination of the activities on fulfilment of national and regional health programmes.

(2) (amend. SG 76/05) The regional health care centres, jointly with the professional organisations, shall study the needs in the sphere of physicians, dental doctors, pharmacists and other medical and non-medical specialists with higher education, and propose to the Minister of Health the number of places for post-graduate studies on basic and profile specialities.

(3) The structure and activity of RHCC shall be settled by regulations issued by the Minister of Health.

Section III. State Health Control

Art. 11. Carried out, for the purpose of preservation of the health of the citizens on the territory of the Republic of Bulgaria, shall be state health control for observation and fulfilment of the established normative health requirements for the sites of public designation, the products, the goods and the activities of importance for the human health and the factors of the living environment.

Art. 12. (1) Bodies of the state health control are the chief health inspector of the Republic of Bulgaria, the regional inspections for preservation and control of the public health (RIPCPH) and the National Centre for radiobiology and radiation protection (NCRRP).

(2) The state health control shall be carried out by state health inspectors who are civil servants of the Ministry of health, RIPCPH and NCRRP.

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

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

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

the Minister of Health by a written order.

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

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

1. the state health control;
2. the activities of health promotion and integrated prophylactics of diseases;
3. the control over the infectious diseases;
4. the measures for protection of the population against the effect of ionising radiation;
5. the prophylactic and anti-epidemic activities in time of calamities, accidents and catastrophes.

(2) The chief state health inspector shall carry out methodological management and control of the units for departmental health control at the Ministry of Defence and the Ministry of Interior.

Art. 15. (1) The state policy of preservation of the public health and the state health control on the territory of the respective region shall be implemented by RIPCPH.

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

(3) The regional inspections for preservation and control of the public health are corporate bodies at budget support - secondary administrators of budget credits with the Minister of Health, with a seat in the settlement - administrative centre of the region.

(4) The regional inspections for preservation and control of the public health shall be established, transformed and closed down by the Council of Ministers.

Art. 16. (1) The regional inspection for preservation and control of the public health shall be managed and represented by a director occupying the position on the grounds of a competition announced by the Minister of Health.

(2) Director of RIPCPH may be a person with educational qualification degree "Master" on medicine, recognised speciality and 5 years practice on the speciality.

(3) The director of RIPCPH shall be given a testimonial every three years by a commission appointed by the Minister of Health. The order of carrying out the testimony shall be determined by the regulation under art. 17, para 2.

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

Art. 17. (1) The regional inspections for preservation and control of the public health shall carry out activities of:

1. control of the observance of the medical requirements for the sites of public designation, the products, the goods and the activities of importance for the human health and the factors of the living environment;
2. control over the infectious diseases;

3. control over the health status of the persons having contact with infected, infection carriers and suspected infectious disease of the persons under art. 34, para 3, as well as of other persons on epidemical indications;

4. health promotion and integrated prophylactics of the diseases;

5. laboratory control of the factors of the living environment and analysing and assessment of their effect on the health of the citizens;

6. observation, assessment and control of the noise in the urbanised territories and public buildings, of pollutants in foodstuffs and drinking water;

7. methodological, consultative and expert assistance in the sphere of preservation of the public health;

8. development and fulfilment of regional programmes and projects in the sphere of preservation of the public health;

9. fulfilment of national programmes and projects in the sphere of preservation of the public health;

10. post-graduate practical studies in the sphere of preservation of the public health.

(2) The structure and activity of RIPCPH shall be settled by a regulation issued by the Minister of Health.

Art. 18. (1) The income of RIPCPH shall be formed by:

1. subsidies from the republican budget;

2. other budget receipts from:

a) fees for the issued documents related to the state health control;

b) paid services requested by individuals or corporate bodies, determined by an ordinance of the Minister of Health.

(2) The resources under para 1, item 2, letter "a" shall be received as an income to the budget of the respective RIPCPH and shall be allocated for support of its activity.

(3) The resources under para 1, item 2, letter "b" shall be received in the Ministry of Health, shall be included in the budgets of RIPCPH and shall be allocated as follows:

1. no less than 60 percent - for financing regional health programmes and acquiring long-term tangible assets for the respective RIPCPH;

2. up to 40 percent - for material stimulation of the employees of the respective RIPCPH.

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

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

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

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

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

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

5. to prescribe removal from work of persons who a sick or infection carriers and

pose danger for the health of the others;

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

7. to place certifying signs in the cases of art. 38 and 39;

8. to draw up acts for establishing administrative offences;

9. to make proposals for compulsory administrative measures stipulated by a law.

(3) The compulsory administrative measures shall be imposed by an order of the directors of RIPCHP.

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

Art. 20. (1) The receipts from fines and material sanctions imposed by penal provisions by the bodies of the state health control shall be received in the budget of the Ministry of health and shall be used for financing national programmes in the sphere of the public health.

(2) Voluntary payment of liabilities having occurred from enacted penal provisions issued by the bodies of the state health control may also be made in the Ministry of Health and in the respective RIPCPH.

(3) The Minister of Health shall administer the receipts from fines and material sanctions under the penal provisions issued by the order of this law, under terms and by an order determined by an ordinance of the Minister of Health and the Minister of Finance.

Section IV. Health Establishments

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

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

1. the national centres for the problems of the public health;

2. the National Expert Physicians Commission (NEPC);

3. the health consulting rooms under art. 26.

(3) The pharmacies are health establishments with a status and activity determined by the Law for the medicines and pharmacies in the human medicine.

Art. 22. (1) The national centres for the problems of the public health are corporate bodies at budget support - secondary administrators of budget credits with the Minister of Health, which shall be opened, transformed and closed down by a decree of the Council of Ministers at a proposal of the Minister of Health.

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

(3) The directors of the national centres for the problems of the public health shall be given testimonial every three years by a commission appointed by the Minister of Health. The

order of carrying out the testimonial shall be determined by the regulations for the structure and activity of the respective national centre for the problems of the public health.

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

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

1. studies, assessment, expertise, analyses and prognoses in the sphere of preservation of the public health;
2. prevention, restriction and liquidation of epidemics of infectious diseases;
3. organising, management and coordination of the medical care in times of calamities, accidents and catastrophes on the territory of the Republic of Bulgaria;
4. assessment of the risk and of the unfavourable impact of the factors of the living environment on the individual, family and public health;
5. laboratory tests and expertise;
6. protection of the persons against the impact of the ionising radiation;
7. health promotion and integrated prophylactics of the diseases;
8. expert, consultative and methodological assistance to the medical and health establishments;
10. planning and implementation of scientific and scientific applied activity;
11. state health control in the cases stipulated by a law;
12. studies.

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

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

1. subsidies from the republican budget;
2. donations and legacies;
3. other budget receipts from:
 - a) paid services requested by individuals or corporate bodies determined by an ordinance of the Minister of Health;
 - b) scientific research and expert activity;
 - c) fees for post-graduate studies.

(2) The resources under para 1, item 3 shall be received in the Ministry of health, shall be included in the budgets of the national centres and shall be allocated as follows:

1. no less than 60 percent - for acquiring long-term tangible assets for the respective national centre;
2. up to 40 percent - for material stimulation of the employees of the respective national centre.

Art. 25. (1) The National Expert Physicians Commission is a corporate body at budget support - a secondary administrator of budget credits with the Minister of health, with a seat in Sofia.

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

(3) The National Expert Physicians Commission shall carry out expert, control methodological and consultative activities on the expertise of the working capacity.

Art. 26. (1) Health and dental surgery may be opened in:

1. the kindergartens and schools;
2. the homes for raising and educating children deprived of parental care at the Minister of Education and Science;
3. the specialised institutions for providing social services - homes for handicapped children and young people, homes for handicapped elderly citizens, the social vocational education establishments, homes for elderly citizens, asylums and homes for temporary accommodation.

(2) The requirements for the structure and activity of the health and dental surgeries shall be determined by an ordinance issued by the Minister of health, coordinated with the Minister of Education and Science, the Minister of Finance, the Minister of Labour and Social Policy and the Minister of Youth and Sport.

(3) The Law for the state budget of the Republic of Bulgaria shall determine annually the financial obligations for the respective year of the state and the municipalities for fulfilment of the activities of the health and dental surgeries.

Section V. Health Information and Documentation

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

(2) (amend. SG 76/05) The medical and health establishments, the RHCC, the RIPCPh, the physicians, dental doctors, pharmacists and other medical specialists, as well as the non-medical specialists with higher non-medical education, working in the national system of health care, shall gather, process, use and store health information.

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

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

1. the therapy of the person continues in another medical establishment;
2. there is a danger for the health or life of other persons;
3. it is necessary for identification of a human corpse or establishing the reasons for the death;
4. it is necessary for the needs of the state health control for prevention of epidemics

and spread of infectious diseases;

5. it is necessary for the needs of the medical expertise and public insurance;

6. it is necessary for the needs of the medical statistics or medical scientific research, after obliteration of the data identifying the patient;

7. it is necessary for the needs of the Ministry of health, the National Centre for Health Information, NHIF, RHCC, RIPCPH and the National Institute of Statistics.

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

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

Chapter two. ACTIVITIES ON HEALTH PRESERVATION

Section I. General Provisions

Art. 29. The state bodies and institutions shall plan, develop and conduct policy, directed to preservation of the health of citizens by ensuring healthy living environment, education in healthy way of life and health prophylactics.

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

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

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

Section II. Ensuring of healthy living environment

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

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

Art. 32. (1) The Minister of Health shall manage the national system for analysis, assessment and control of the noise in the urbanised territories and the public buildings, the

pollutants in the foods and in the potable waters.

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

(3) The regional inspectorates for preservation and control of public health shall monitor, analyse and assess the factors of the living environment on the territory of the region and propose measures for restricting of their harmful impact on the health of the citizens.

(4) The state bodies, implementing analysis, assessment and control of the parameters of the environment, shall concede to the Minister of Health the data, necessary for implementing assessment of the health risk.

Art. 33. (1) The Council of Ministers shall, upon proposal by the Minister of Health and the Minister of Environment and Waters, determine at every three years the regions in the country with increased health risk.

(2) The Council of Ministers shall approve programmes for organising control investigations and examinations, conducting of activities, connected with strengthening and restoration of the health of the citizens, who live in the regions with increased health risk.

Art. 34. (1) The health requirements at designing and construction of sites with public designation shall be determined with an ordinance by the Minister of Health and the Minister of Regional Development and Public Works.

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

(3) The health requirements to the persons, working in the children's establishments, the specialised institutions for children and aged people, the water supply sites, the enterprises, producing or trading with foods, the barber's, the hairdresser's and the cosmetic parlours shall be determined with an ordinance by the Minister of Health.

Art. 35. The bodies of the state health control shall participate in the expert councils for spatial planning, coordinate if necessary the development schemes and plans, participate in the assessment of the compliance of the investment designs when it is implemented with approval by expert council of the approving administration or upon request by individuals or corporate bodies, give statement on the readiness of the construction for entering into exploitation by the order of the Law of spatial planning.

Art. 36. (1) Anybody, who opens site with public designation, shall be obliged to notify about this the respective RIPCPH at the location of the site in 7 days term after the starting of the activity, pointing out the address of the site, the kinds of activity, implemented in it, as well as the name of and the permanent address of the person, who exercises the activity, and for the traders - the data from the court registration.

(2) In three months term after the notification the territorial bodies of the state health control shall implement check for observing the health requirements in the site.

(3) The regional inspectorates for preservation and control of public health shall create and keep public register of the sites with public designation under conditions and by order, determined with an ordinance by the Minister of Health.

(4) Para 1 shall not be applied for medical establishments, enterprises for production and wholesale trade with medicines, pharmacies, drugstores, enterprises for production, preservation and trade with foods and for sites for public catering.

Art. 37. (1) Upon request by the interested persons the state health inspector shall issue health certificate for export of products and goods of importance for human health, which certifies the observing of the normatively established requirements for production of the products and the goods of importance for human health.

(2) The Minister of Health shall determine with an ordinance the order for issuing of health certificate for export of products and the goods of importance for human health.

(3) Upon doubt of the safety of products and goods of importance for human health from import the customs bodies shall have right not to admit them on the territory of the Republic of Bulgaria. These products and goods shall be imported after presenting of statement by RIPCPH about their safety.

Art. 38. (1) Upon not observing of the health requirements in sites of public designation or upon implementing of activities of importance for human health the state health inspectors shall give obligatory prescriptions and determine term for removal of the breaches.

(2) Upon not fulfilment of the obligatory prescriptions in the defined term the director of RIPCPH, respectively the director of NCRPP, shall issue order for stopping the exploitation of the site or parts of it or for stopping of the respective activity till removal of the breaches.

(3) In the cases when there is immediate danger to the life and the health of people, for dissemination of infectious diseases or for occurrence of poisoning, the state health inspectors shall stop immediately with a prescription the exploitation of the site or parts of it or the respective activity, determine measures for removal of the breaches and immediately notify the director of RIPCPH.

(4) The director of RIPCPH, respectively the director of NCRPP, shall in 24 hours term after the stopping of the site issue order, with which is confirmed or revoked the given prescription for stopping the exploitation of the site or the respective activity.

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

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

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

2. take samples for laboratory analysis and expertise in the presence of the interested person or his representative and present them in the laboratory of RIPCPH.

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

(3) At contesting of the results from the laboratory analyses and the expertise second investigations shall be implemented upon written request by the interested person, made to the chief state health inspector through the director of RIPCPH in three days term after the date of receiving the result from the initial investigation.

(4) In the cases of para 3 the second investigations shall be implemented by other RIPCPH, determined by the chief state health inspector.

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

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

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

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

Art. 42. (1) Order for reprocessing, use for other purposes or destroying of products or goods of importance for human health shall be issued by the director of RIPCPH or NCRRP - for products or goods with value up to 100 000 levs, and by the chief state health inspector - for products and goods with value over 100 000 levs.

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

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

(2) The laboratory investigations for the needs of the state health control shall be for the account of RIPCPH.

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

Art. 45. (1) The compulsory administrative measures, imposed by the order of this

section, shall be appealed by the order of the Law of the administrative procedures. The compulsory administrative measures shall be subject to preliminary execution.

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

1. these, decreed by state health inspector - before the director of RIPCPH and the director of NCRRP;

2. these, decreed by the director of RIPCPH and NCRRP - before the chief state health inspector;

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

Art. 46. For issuing of documents by the bodies of state health control fees shall be paid, determined with tariff of the Council of Ministers.

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

Art. 48. The bodies of the Ministry of Interior, the other state and municipal bodies and the chiefs of the departments and the organisations shall be obliged to render the necessary assistance and cooperation to the state health inspectors at exercising their authorities.

Section III.

Health requirements to the cosmetic products

Art. 49. (1) The cosmetic products, offered on the market must not cause damage to human health when they are applied in compliance with their designation, the instruction for use and destroying as well as with all other instructions, conceded by the producer or the importer.

(2) The requirements for production, packing, labelling, advertising, putting and offering on the market of the cosmetic products shall be determined with an ordinance, issued by the Minister of Health in coordination with the Minister of Economy.

Art. 50. With a permission by the chief state health inspector at the labelling the producers and the importers may not point out one or more of the components of a cosmetic product for a period of 5 years with objective preservation of the commercial secret.

Art. 51. (1) For receiving permission the interested persons shall submit application to the chief state health inspector of the Republic of Bulgaria, to which shall be attached proofs for safety of the component, determined in the ordinance of art. 49, para 2.

(2) The chief state health inspector shall issue permission for or motivated refusal in term up to two months after the submitting of the documents of para 1. The refusal shall be subject to appeal by the order of the Law of the administrative procedures.

(3) Upon existence of important reasons the interested persons can require by the

order of para 1 and 2 extension of the term of the issued objection for a term not longer than three years.

Art. 52. (1) The producer or the importer of the cosmetic product shall notify timely the chief state health inspector about all changes in the circumstances, under which the permission of art. 50 has been given.

(2) Upon change of the name of the cosmetic product, containing unannounced component, the producer or the importer shall notify the chief state health inspector not later than 15 days before the placing of the product on the market.

(3) Upon establishing of non compliance with the requirements for safety of the health of the users as well as in the cases of occurrence of data from science and practice about health risk, connected with the unannounced component the chief state health inspector shall divest the issued permission.

Section IV.

Activities for impact over factors risky for the health

Art. 53. (1) The Minister of Health and other competent state bodies shall together with the no government organisations create conditions for restriction of smoking, abuse of alcohol and not admitting the use of narcotic substances by:

1. implementing promotional and prophylactic activities;
2. ensuring access to medical help and social protection of the affected persons.

(2) The activities of para 1 shall be implemented through national programmes for restricting of smoking, the abuse of alcohol and not admitting the use of narcotic substances.

(3) One percent of the resources, received in the republican budget from the excise duties on the tobacco products and the alcohol beverages, shall be used for financing of the national programmes for restricting of smoking, the abuse of alcohol and not admitting the use of narcotic substances.

(4) The municipalities shall approve and implement regional programmes for restricting of smoking, the abuse of alcohol and not admitting the use of narcotic substances.

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

1. to persons below 18 years of age;
2. to persons in drunk state;
3. on the territory of the kindergartens, schools, hostels for students, medical establishments;
4. at sport events;
5. at public events, organised for children and students.

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

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

1. be directed to persons below 18 years of age, as well as be transmitted in programmes or published in printed publications, designated for them;

2. use persons below 18 years of age as participants;
 3. connect the use of alcohol beverages with sport or physical achievements or with driving of vehicles;
 4. contain claims about usefulness for health, social or sexual well-being or present the abstention or the temperance in negative aspect.
- (4) The indirect advertisement of spirit beverages cannot be transmitted in radio and television programmes before 22.00 hours.

Art. 56. (1) Smoking shall be prohibited in the covered public places, including the public transport and the covered working premises.

(2) The Council of Ministers shall determine with an ordinance the conditions and the order, under which will be admitted as exception smoking in detached zones of the places of para 1.

Section V. Control over the infectious diseases

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

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

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

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

1. obligatory planned immunisations and re-immunisations, included in the immunisation calendar of the Republic of Bulgaria;
2. purposed immunisations and re-immunisations, which shall be implemented upon special indications;
3. recommended immunisations.

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

Art. 59. Upon occurrence of extraordinary epidemic situation as well as upon registration of significant reduction of the immunisation coverage the Minister of Health can order:

1. obligatory immunisations and re-immunisations for defined groups of the population, which are not included in the immunisation calendar;
2. obligatory immunisations and re-immunisations with preparations, which are not included in the immunisation calendar;
3. immunisations and re-immunisations by order and way, different from these, pointed out in the immunisation calendar;

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

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

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

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

(4) The organisation of the prophylactics and the control of the inter-hospital infections shall be determined with an ordinance by the Minister of Health.

(5) The Minister of Health shall determine with an ordinance the order and the conditions for conducting diagnostics, prophylactics and control of separate infectious diseases.

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

Art. 61. (1) Persons, ill and infected with cholera, plague, smallpox, yellow fever, virus haemorrhage fevers, diphtheria, typhoid fever, poliomyelitis, brucellosis, anthrax, malaria, severe acute respiratory syndrome and tuberculosis with secretion of bacilli, shall be subject to compulsory isolation and hospital treatment.

(2) When there is threat for the health of the citizens the Minister of Health can order compulsory isolation of ill with diseases out of these, pointed out in para 1.

(3) The compulsory isolation and the treatment of the persons of para 1 and 2 shall be implemented with order by the chief of the respective medical establishment upon proposal by the healing doctor.

(4) Isolation and treatment of ill with infectious diseases out of these, pointed out in para 1, can be implemented in home conditions after assessment by the existing epidemic risk by epidemiologist and specialist in infectious diseases.

Art. 62. (1) The individuals and the corporate bodies, who implement activities for disinfection, disinsection and deratisation, shall notify about this the Ministry of Health in 14 days term after starting of the activity.

(2) The conditions and the order for implementing the activities of para 1 shall be determined with an order by the Minister of Health.

Art. 63. (1) Upon occurrence of extraordinary epidemic situation the Minister of Health shall introduce anti-epidemic measures on the territory of the country or separate region.

(2) measures of para 1 on the territory of a separate municipality can be introduced also by the mayor upon proposal by the director of the respective RIPCPH.

(3) The state and the municipal bodies shall create the necessary conditions for fulfilment of the measures of para 1 and the resources for their implementation shall be

ensured from the republican budget, respectively from the municipal budgets.

(4) Upon danger from occurrence and epidemic dissemination of infectious diseases the state bodies, the municipalities, the individuals and the corporate bodies shall be obliged to render full cooperation to the bodies for state health control.

Section VI. Protection from the impact of ionising radiations

Art. 64. (1) The protection of the persons from the impact of ionising radiations shall be implemented observing the principles of radiation protection in compliance with this law and the Law of safe use of nuclear energy.

(2) The protection of para 1 shall include:

1. control of the factors of the working and the living environment for determining and reduction of the radiation of persons from sources of ionising radiations;
2. medical observation of the persons, who work with sources of ionising radiations;
3. dosimetric control for determining the internal and the external radiation of the persons, who work with sources of ionising radiations;
4. assessment of the radiation and the radiation risk of the population as a whole and of groups from it;
5. medical monitoring of the persons, radiated with sources of ionising radiations at medical examinations or treatment;
6. medical ensuring of the public, of separate groups from it and of the persons, who work with sources of ionising radiations, in the cases of radiation accident.

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

1. the conditions and the order for medical ensuring and health norms for protection of the persons in case of radiation accident;
2. the conditions and the order for ensuring of protection for the persons at medical radiation;
3. the conditions and the order for implementing individual dosimetric control of the persons, working with sources of ionising radiations;
4. the health norms and requirements at work in ambience of ionising radiations;
5. requirements for protection of the persons at chronic radiation as result of production, trade and use of raw materials, subjects and goods with increased content of radio-nuclides.

(2) The persons, fallen ill as result of radiation accident or radiation pollution of environment, shall be subject to monitoring and treatment under conditions and by order, determined with an ordinance by the Minister of Health.

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

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

(2) Medical radiation with sources of ionising radiations shall be admitted with regard

to persons, who conscientiously and voluntarily render help to other persons in the process of medical radiation without this being their professional obligation.

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

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

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

Art. 67. (1) Implementing of medical radiation with sources of ionising radiations at implementing medical legal procedures with persons, against whom punitive procedure has been formed, shall be admitted.

(2) Medical radiation of para 1 shall be ordered by the competent state body after conclusion by a doctor that the person has no medical contraindications for this.

(3) The conditions and the order for conducting of medical radiation of the persons of para 1 shall be determined with an ordinance by the Minister of Health, the Minister of Finance and the Minister of Justice.

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

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

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

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

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

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

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

monitoring.

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

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

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

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

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

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

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

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

Section VII.

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

Art. 73. (1) The activities for destroying or dismantling of asbestos and/or asbestos containing materials from buildings, constructions, enterprises, installations or ships shall be implemented after receiving permission from the director of RIPCPH, on which territory they are implemented.

(2) For receiving permission the interested person shall submit to RIPCPH application, to which shall be attached plan of the work for destroying or dismantling and list of the engaged workers.

(3) In the plan for work shall be determined the measures, necessary for ensuring the safety and the health of the workers, providing also dismantling of the asbestos and/or the asbestos containing materials before applying of techniques for destroying everywhere it is practically possible, and ensuring personal protection means, where necessary. The plan shall include the characteristics of the used equipment for protection of the personnel, implementing work with asbestos, for protection of other persons, who are at the place of the implemented work or a close to it, and for removal of the pollution with asbestos dust.

(4) In the plan for work shall be pointed out the place of implementation, the kind and the expected duration of the activities, the working processes, including work with asbestos or asbestos containing materials, and the provided measures for protection of environment.

(5) Permission shall not be required at implementing accident - rescue activities.

Art. 74. (1) In 10 days term after submitting of the application the director of RIPCPH shall send in official way the documents of art. 73, para 2 for statement to the regional inspectorate for environment and waters, on which territory is located the site for destroying or dismantling of asbestos or asbestos containing materials.

(2) The regional inspectorate for environment and waters shall give statement in 14 days term from the date of receiving the documents. In case in the term, defined by RIPCPH statement is not received, it shall be considered that the regional inspectorate for environment and waters coordinates the presented documents without note.

(3) The director of RIPCPH shall notify the applicant about the recommendations of RIPCPH and/or the regional inspectorate for environment and waters about changes in the plan for work. In compliance with the recommendations in term not later than one month after the notification the applicant shall, be obliged to present the corrected plan for work in compliance with the recommendations.

(4) The permission for destroying or dismantling of asbestos or asbestos containing materials shall be issued by the director of RIPCPH in 5 days term after receiving positive statement by the regional inspectorate for environment and waters or receiving of the corrected plan for work.

(5) In the cases of non fulfilment of the recommendations the director of RIPCPH shall make motivated refusal for issuing of permission.

Section VIII.

Resort resources and resorts

Art. 75. (1) Resort resources shall be the mineral waters, the healing peloids, the coastal beach strip and the localities with bio-climatic conditions, favourable for prophylactics, treatment and rehabilitation.

(2) Healing preloads are the firth - lagoon slimes, the spring slimes, the turf and the bentonite clays.

Art. 76. (1) The territories with categorised resort resources and opportunities for construction and exploitation of sites and facilities for prophylactics, healing, rehabilitation, recreation and tourism of the population shall be announced as resort.

(2) The boundaries and the conditions for development of the resort shall be determined with decision of the Council of Ministers, which shall be determined in State Gazette.

Art. 77. (amend. SG 94/05) The Minister of Health shall together with the Minister of Regional Development and Public Works, the Minister of Environment and Waters and the chairman of the State agency for tourism determine with ordinances the conditions and the order for:

1. the use and the preservation of the mineral waters, the healing peloids, the coastal beach strip and the localities with bio-climatic conditions, favourable for prophylactics,

treatment and rehabilitation, as well as for determining the capacity of the coastal beach strip and the localities with bio-climatic conditions, favourable for prophylactics, treatment and rehabilitation;

2. the approval of guarding zones and guarding regime for preservation of the deposits of the healing peloids, the coastal beach strip and the localities with bio-climatic conditions, favourable for prophylactics, treatment and rehabilitation;

3. the approval of exploitation reserves and the use of the healing slime deposits;

4. the exploitation on the beaches along the Black sea coast.

Art. 78. (1) The medical establishments shall use mineral waters and healing slime for implementing their healing activity, including in the cases when these resort resources are granted under the law of concessions.

(2) The quantities of mineral water and healing slime of para 1 shall be determined every year upon proposal by the Minister of Health with a decision of the Council of Ministers.

Chapter three. MEDICAL SERVICING

Section I. Accessibility and quality of the medical care

Art. 79. The medical care in the Republic of Bulgaria shall be implemented by applying methods and technologies, approved by the medical science and practice.

Art. 80. (amend. SG 76/05) The quality of the medical care shall be based on medical standards, approved by the order of art. 6, para 1 of the Law of the medical establishments and the Rules for good medical practice, approved and authorised by the order of art. 5, item 4 of the Law of the professional organisations of the physicians and the dental doctors.

Art. 81. (1) Each Bulgarian citizen shall have right to accessible medical care under the conditions and by the order of the Law of the health insurance.

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

1. timeliness, sufficiency and quality of the medical care;

2. equality at rendering medical care with priority for children, pregnant and mothers of children up to 1 year of age;

3. cooperation, consistency and coordination of the activities between the medical establishments;

4. respect to the rights of the patient.

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

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

1. medical aid at emergency status;
2. stationary psychiatric care;
3. ensuring blood and blood products;
4. transplantation of organs, tissues and cells;
5. compulsory treatment and/or compulsory isolation;
6. expertises for degree of damages and durable inability to work;
7. medical transport by order, determined by the Minister of Health.

(2) Each Bulgarian citizen shall use:

1. vaccines for obligatory immunisations and re-immunisations, vaccines at special indications and upon extraordinary circumstances, specific serums, immuno-globulins and other bio-products, connected with the prophylactics of the infectious diseases as well as the technical means for their application;

2. full amount of anti-epidemic activities;

3. access to health activities, included in national, regional and municipal health programmes.

(3) The children up to 16 years of age shall have right to medical care out of the scope of the obligatory health insurance.

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

(5) The activities of para 1, 2, 3 and 4 shall be financed from the republican budget and from the municipal budgets and they shall be used under conditions and by order, determined with an ordinance by the Minister of Health.

Art. 83. (3) The foreigners, to whom long stay in the Republic of Bulgaria is permitted, except the persons of art. 24, para 1, items 5, 7, 8, 9, 10, 13, 14 and 16 of the Law of the foreigners in the Republic of Bulgaria, shall use medical care of art. 81 and 82 equally with the Bulgarian citizens.

(2) Out of the cases of para 1 the foreigners, who stay in the Republic of Bulgaria, shall pay the value of the medical care, rendered to them, at prices, determined by the medical establishment, under conditions and by order, regulated with an ordinance by the Minister of Health, the Minister of Foreign Affairs and Minister of Justice.

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

(4) In the cases when the obligatory insurance of para 3 is concluded a entering the country the general conditions, the minimum insurance sum, the minimum insurance premium and the order shall be determined with an ordinance by the Council of Ministers.

Section II. Rights and obligations of the patient

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

rendered medical care.

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

Art. 85. Assessment of the health status of the patient cannot be based on race, sex, age, ethnic belonging, origin, religion, education, culture level, beliefs, political affiliation, sexual orientation, personal and public status or proprietary status.

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

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

(2) At hospitalisation the patient shall have right:

1. to be visited by his personal doctor and by the specialist, issued direction for hospitalisation;
2. to receive or refuse visits;
3. to use the services of psychotherapist, lawyer and clergyman;
4. to education and access to activities, responding to his social, religious and cultural needs;
5. to receive information about the price of each medical service, manipulation, treatment and the medical preparations in the pre-hospital and the hospital care.

(3) The rights of the patient shall be exercised observing the regulation for the structure, the activity and the internal order of the medical establishment.

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

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

(3) When the patient is young or judicially incapable the informed consent shall be expressed by his parent or guardian except in the cases provided with a law.

(4) For persons with psychic disorders and established inability to express informed consent it shall be expressed by the persons, determined by the order of art. 162, para 3.

Art. 88. (1) For receiving informed consent the doctor (stomatologist) in charge shall notify the patient, respectively his parent, guardian or trustee, as well as the persons of art. 162, para 3, about:

1. the diagnosis and the character of the disease;
2. description of the purposes and the nature of the healing, the reasonable alternatives, the expected results and the prognosis;
3. the potential risks, connected with the proposed diagnostic - healing methods, including the side effects and the unwanted medical reactions, pain and other discomforts;
4. the probability of favourable influence, the risk for the health at applying of other methods of treatment or at refusal of treatment.

(2) The medical information of para 1 shall be conceded to the patient, respectively to his parent, guardian or trustee, as well as to the persons of art. 162, para 3 timely and in appropriate amount and form, giving opportunity for freedom of the choice of treatment.

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

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

1. his physical or psychic status does not allow expressing of informed consent;
2. it is impossible to be achieved informed consent by parent, guardian or trustee or by the person of art. 162, para 3 in the cases the law requires it.

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

Art. 90. (1) The patient, respectively his parent, guardian or trustee or the person of art. 162, para 3, can refuse at any time the proposed medical care or the continuation of the started medical activity.

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

(3) If the person, respectively his parent, guardian or trustee or the person of art. 162, para 2, is not in capacity or refuses to certify in writing the refusal of para 1, this shall be certified with signature by the healing doctor and a witness.

(4) In the cases when under para 1 there is refusal by a parent, guardian or trustee and the life of the patient is threatened, the chief of the medical establishment can take decision for implementing life saving treatment.

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

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

1. his health and the need of treatment;
2. the disease, on the occasion of which he has looked for health care, and its prognosis;
3. the planned prophylactic, diagnostic, healing and rehabilitation activities as well as

the risks, connected with them;

4. the diagnostic and the therapeutic alternatives;
5. the name, the position and the speciality of the persons, who participate in the diagnostic - healing process.

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

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

Art. 93. (1) The patient, respectively his parent, guardian or trustee or person, authorised by him, shall have right to submit appeals and signals to RHC upon breaching of his rights under this law or at disputes, connected with the medical servicing.

(2) The regional centre for health care shall in 7 days term make official check for the appeal or the signal.

(3) Upon establishing of administrative breach the checking employee of RHC shall compile act for establishing of the administrative breach and the director of RHC shall issue punitive decree by the order of the Law of the administrative offences and sanctions.

(4) (amend. SG 76/05) Upon establishing of administrative breaches, punitive by the order of the Law of the professional organisations of the physicians and the dental doctors and the Law of health insurance, the RHC shall notify and send the appeal to the regional colleges of the Bulgarian physicians' union and the Union of the stomatologists in Bulgaria and to the regional health insurance fund.

(5) In three days term after finishing the check the RHC shall notify the patient about the results from the check and the undertaken activities.

Art. 94. The patient shall be obliged:

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

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

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

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

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

(2) Palliative medical care shall be rendered by the personal physician, by medical establishments for off hospital and hospital care, by dispensaries and hospices.

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

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

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

(2) Pathological - anatomic autopsy of persons, deceased out of medical establishment, can be implemented upon request by the physician, who has established the death or upon request by the relatives of the deceased.

(3) Upon explicit request by the relatives of the deceased the chief of the medical establishment can issue order for exemption from pathological - anatomic autopsy.

(4) The pathological - anatomic autopsy shall not be implemented when the corpse is subject to judicial medical expertise.

Section III. Medical care upon emergency status

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

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

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

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

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

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

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

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

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

Section IV. Medical expertise

Art. 101. (1) Medical expertise shall be implemented for establishing the degree of reduced ability to work and for confirmation of professional disease.

(2) The medical expertise shall be organised and managed by the Minister of Health and RHC.

(3) The degree of durably reduced ability to work and the degree of the reduced ability of social adaptation of the children up to 16 years of age shall be determined in percentage with regard to the abilities of the healthy person.

(4) The degree of durably reduced ability to work of persons, rounded 65 years of age, shall be determined for life. Re-certification of these persons can be implemented upon their wish or upon request by the control bodies of the medical expertise.

(5) The principles and the criteria of the medical expertise as well as the order for establishing the degree of reduced ability to work and for confirmation of professional disease, shall be determined with ordinances by the Council of Ministers.

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

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

2. implement coordination of the activities between the state bodies in connection with the medical expertise;

3. analyse information about the activity, the development and the status of the medical expertise in the country;

4. develop and present for approval to the Council of Ministers drafts of amendment and supplement of normative acts, related to the medical expertise;

5. develop methodology for financing and control over the activities of the bodies of the medical expertise, which shall be approved by the Council of Ministers.

(2) The members of the National council in medical expertise shall include: deputy Prime Minister, who is chairman of the council, the Minister of Health, the Minister of Labour and Social Policy, the Minister of Finance, the manager of the National Insurance Institute, the director of the NHIF and the director of NEMC.

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

Art. 103. (1) The medical expertise of the ability to work shall include expertise of the temporary inability to work and expertise of the durably reduced ability to work.

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

(3) The expertise of the durably reduced ability to work and the professional diseases shall be implemented by TEMC and NEMC.

(4) the expertise of the degree of the reduced ability of social adaptation of the children up to 16 years of age shall be implemented by TEMC with the participation of

specialists if children's diseases and social workers.

Art. 104. (1) The medical consultative commissions shall be opened and closed with an order by the directors of RHC in medical establishments for off hospital and hospital care upon proposal by the chief of the respective medical establishment.

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

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

Art. 105. (1) The territorial expert medical commissions shall be opened and closed by the directors of RHC in coordination with the Minister of Health at state and municipal medical establishments for hospital care and dispensaries.

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

(3) In the members of each TEMC shall obligatory be included: doctor -representative of the respective territorial division of NII, determined with an order by the chief of the respective territorial division of NII, and representative of regional directorate for social support, determined with an order by the director of the respective regional directorate for social support.

Art. 106. (1) In the TEMC and NEMC shall work doctors with recognised speciality and not less than 10 years labour practice in the respective profile.

(2) In the specialised teams of NEMC shall obligatory be included a doctor - representative of NII, determined with an order by the manager of NII.

(3) the members of TEMC and NEMC cannot exercise activities subject to their control and implement consultative activity, related to expertise of temporary and durably reduced ability to work.

Art. 107. (1) For implementing the activity of TEMC the director of the medical establishment shall conclude contract for financing with the Minister of Health.

(2) The highly specialised and expensive medical - diagnostic investigations, connected with the process of the medical expertise of the ability to work, shall upon request by TEMC and NEMC be financed by NHIF within the framework of its annual budget.

Art. 108. (1) The activity for registration, processing and preservation of health information about the persons, certified by TEMC and NEMC, shall be implemented by regional card-index of the medical expertises (RCME).

(2) the regional card-indexes of the medical expertises shall be structural units of RHC.

(3) The medical documentation of the persons, certified by TEMC and NEMC, to whom percentage of durably reduced ability to work has been determined, shall be preserved

for 40 years after the last decision of TEMC (NEMC) and of all other persons - 5 years.

(5) Copy of the decisions of TEMC and NEMC shall be sent to the National centre for health information.

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

Art. 110. Control over the medical expertise shall be implemented by the National centre for medical expertise, by the Minister of Health, the Minister of Labour and Social Policy, NHIF, NII the regional councils of art. 111 and by RHC.

Art. 111. (1) For control over the acts, issued by the bodies for expertise of the temporary inability to work, with an order of the director of the respective RHC shall be created regional council, including representatives of RHC, the territorial division of NII and RHIF. The regional council shall also implement checks of not less than 2 percent of the decisions, issued on the territory of the respective region, for temporary inability to work, chosen by random principle.

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

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

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

Art. 112. (1) The appeals and the objections on behalf of the interested persons and bodies (the certified, the insurers, NII, the Agency for social support, fund "rehabilitation and social integration" and the bodies of the medical expertise of the ability to work) shall be made:

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

2. against the decisions of the MCC - in 14 days term after receiving them before TEMC;

3. against the decisions of TEMC - in 14 days term after receiving them before NEMC;

4. against the decisions of NEMC - before the Sofia city court by the order of the Law of the administrative procedures.

(2) The interested persons and organisations (the certified, the insurers, the territorial divisions of NII and NHIF) can appeal in 14 days term decisions of MCC, with which are

breached the requirements and the order at issuing expert decisions for temporary inability to work, also before the regional council of art. 111.

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

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

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

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

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

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

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

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

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

Section V.

Medical ensuring at disasters, accidents and catastrophes

Art. 114. (1) The management, the organisation and the resource ensuring of the health care at disasters, accidents and catastrophes shall be implemented by the Minister of Health, the directors of RHC, the bodies for state health control, the medical and the health establishments.

(2) The bodies of para 1 shall conduct the activity for the medical ensuring at disasters, accidents and catastrophes in close interaction with the Permanent commission for protection of the population at disasters, accidents and catastrophes at the Council of Ministers, with the bodies of the central and the local power, with State agency "Civil defence", with the non government organisations and with the Bulgarian Red Cross.

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

(2) On the basis of the action plans at disasters, accidents and catastrophes, approved

by the Council of Ministers, the bodies of art. 114, para 1, shall:

1. create the necessary conditions for medical sorting, primary processing, treatment, rehabilitation and medical expertise of the damaged;
2. form and prepare bodies for management and teams for medical care;
3. ensure the protection of the stationary ill and the medical staff from external factors;
4. organise and implement anti-epidemic and hygienic activities and sanitary control on the affected territory;
5. form stocks for resource ensuring of the medical activities;
6. organise the continuing training of the medical specialists and the population in rendering medical care upon disasters, accidents and catastrophes.

(3) The financial ensuring of the health care at disasters, accidents and catastrophes shall be implemented from the republican budget.

Art. 116. (1) for implementing the medical ensuring at disasters, accidents and catastrophes at the director of RHC shall be created council for medical ensuring at disasters, accidents and catastrophes.

(2) The council of para 1 shall include the directors of RIPCPH, of the medical establishments for hospital care, of the centre for emergency medical care and representatives of the regional administration and of the municipalities in the respective region.

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

Chapter four. NATIONAL SYSTEM OF HEALTH CARE

Section I. Health protection of children

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

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

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

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

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

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

(2) the maintenance of the children in the municipal creches and the activity of the municipal children's kitchens shall be supported by the respective municipal budget.

(3) For bringing up the children in the municipal creches as well as for receiving children's food from the municipal children's kitchens the parents and the guardians shall pay fees in amounts, determined by the municipal council in compliance with the Law of the local taxes and fees.

Art. 120. (1) The health offices in the kindergartens, the schools, the homes for bringing up and training of children and the specialised institutions for children shall implement activities for:

1. medical observation;
2. health education and forming health habits;
3. rendering first medical aid;
4. control over the hygiene status of the children;
5. control over the hygiene status of the premises and the food;
6. preparing and maintaining of medical documentation.

(2) The conditions and the order for preparing, processing and preservation of the medical documentation in the health offices shall be determined with the ordinance of art. 26, para 2.

(3) The activities in the health offices shall be implemented by doctor, medical officer or nurse.

(4) The control over the activity of the health offices shall be implemented by the respective RHC.

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

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

1. personal hygiene;
2. healthy feeding;
3. healthy living environment;
4. healthy way of life;
5. protection from infectious diseases;
6. health risks at tobacco smoking, use of alcohol and narcotic substances;
7. sexual conduct, protection from sexually transferred diseases and AIDS and protection from unwanted pregnancy;
8. first aid for injured.

(2) The training of the lecturers in the issues of para 1 shall be organised by the Minister of Education and Science according to study programmes, coordinated with the Minister of Health.

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

Art. 123. (1) For ensuring prophylactic medical and stomatological aid to the children and the students in the creches, the kindergartens, the schools, the homes for bringing up and training of children, deprived from parents' care, and in the specialised institutions for children once in the year shall be required documents for carried out examinations or prophylactic medical and stomatological examinations shall be implemented.

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

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

Art. 124. (1) The prophylactic medical care for the children, accommodated at the homes for medical - social care for children, shall be implemented by doctors, working at the medical establishment.

(2) The stomatological treatment, out of the scope of the National framework agreement, of the children from the specialised institutions for children, opened by the Ministry of Health, the Ministry of Education and Science, the Ministry of Labour and Social Policy, the Ministry of Interior and the Ministry of Justice, as well as by the specialised institutions for children, managed by the municipalities, shall be paid by the respective departments.

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

Section II. Reproductive health

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

1. promotion and consultations for preservation of the reproductive health of children and persons in reproductive age;

2. ensuring of access to specialised consultative assistance on the issues of reproductive health and family planning;

3. prophylactics and treatment of sterility;

4. specialised information, consultations, prophylactics and treatment of the sexually transferred diseases and AIDS;

5. prophylactics, treatment and dispensary observation of persons with malignant diseases of the reproductive system.

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

reproductive health.

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

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

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

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

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

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

Section III. Assisted reproduction

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

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

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

(3) The assisted reproduction shall be implemented according to the approved medical standards.

Art. 131. (1) The medical establishments shall implement all medical activities, connected with the choice, the preparation of the potential recipient and his durable observation, and control his health status and the maintaining treatment of the recipient till the birth of the foetus.

(2) The conditions and the order for expertise, preservation, processing, taking and conceding of ova, spermatozoids and fertile ova shall be determined with ordinance by the Minister of Health.

Art. 132. (1) The medical establishments, implementing activities for assisted reproduction, shall keep official register, including data about:

1. the persons, who are donors or recipients;
2. the fertile ova and data about their donors;
3. the results of the implemented assisted reproduction, medical data about the health status of the recipient and the born child.

(2) The dissemination of data, which can serve for identification of the donors or the recipients of ova or spermatozoids when the donor is a person, different from the man or the woman, willing to create generation, shall be prohibited except in the cases, provided with a law.

(3) The data from the register of para 1 shall be official information and they shall be preserved for 30 years.

(4) The order for registration, processing, preservation and conceding of the information from the register of para 1 shall be determined with the ordinance of art. 131, para 2.

Art. 133. Artificial insemination of ovum with spermatozoids from a donor, who is in blood relation in direct line and in lateral line up to fourth degree with the woman, by whom is the ovum, shall not be admitted. The circumstance shall be established with written declaration by the persons, willing to create generation.

Art. 134. Ova, spermatozoids and fertile ova, which are not used for creating of generation, can be conceded to scientific, educational and medical establishments in the country and abroad for medical, scientific and educational purposes after receiving written informed consent by the donor and upon fertile ovum - by both of the donors, by an order, determined with an ordinance by the Minister of Health.

Art. 135. (1) The use of techniques for assisted reproduction with purpose selection of the sex of the generation, except in the cases when inherited diseases, connected with the sex, must be prevented, shall be prohibited.

(2) The use of techniques for assisted reproduction, aiming transfer of genetic information only from one individual in his generation shall be prohibited.

(3) The reproductive cloning of people, including with purpose donation of organs, tissues and cells, shall be prohibited.

(4) Intervention, directed to modification of the human genome, can be undertaken only with prophylactic or healing purpose but not for introduction of modification in the genome of the generation.

Art. 136. each form of discrimination against a person, based on his genome, shall be prohibited.

Section IV. Genetic health and genetic investigations

Art. 137. The preservation of the genetic health shall be ensured by conducting health activities, directed to:

1. prophylactic and diagnostic investigations for proving and classification of genetic diseases;
2. dispensary system for the persons with increased risk of occurrence and development of genetic diseases;
3. healing of inherited diseases, innate anomalies and predisposition;
4. establishing of inherited characteristics and identification of parent;
5. preservation of genetic information.

Art. 138. Prophylactic genetic investigations shall be implemented for:

1. determining the risk of occurrence of genetic disease in the generation;
2. identification of clinically healthy carriers of genetic deviations;
3. diagnostics of inherited and other diseases in the periods before and during the pregnancy and after the childbirth.

Art. 139. (1) The genetic investigations in the period before the childbirth shall be implemented upon proven risk for transfer of genetic disease in the generation.

(2) The investigations of para 1 shall be implemented under the control of a doctor and they shall include:

1. proving of genetic deviations of clinically healthy and of ill parents;
2. establishing of predisposition for to genetic disease;
3. establishing of genetic deviations, occurred due to the way of life or the external environment;
4. proving of genetic diseases at their clinical manifestation.

Art. 140. For establishing the kind and the frequency of the genetic deviations and determining the genetic fund by national health programmes purposed investigations shall be carried out.

Art. 141. (1) Genetic investigations and taking of biological material for genetic investigations for medical or scientific purposes shall be conducted only after receiving of written informed consent by the investigated persons.

(2) Genetic investigations of children, persons with psychic disorders and persons under interdict, shall be implemented also after permission by the commission in medical ethics at the respective medical establishment.

(3) The results from conducted genetic investigations and screening cannot be basis

for discrimination of the investigated persons.

(4) The data about the human genome of the persons shall be personal data and they cannot be conceded to employers, health insuring organisations and insurance companies.

Art. 142. (1) genetic investigations for medical or scientific purposes shall be implemented by accredited:

1. genetic laboratories at medical establishments for hospital care;
2. genetic laboratories at medical establishments for off hospital care;
3. independent laboratories.

(2) The Minister of Health shall determine with an order National genetic laboratory.

(3) The laboratory of para 2 shall implement methodical guidance and control over the activity of the genetic laboratories.

(4) The National genetic laboratory shall create and maintain national genetic register.

(5) The conditions and the order for work of the National genetic laboratory and the register of para 4 shall be determined with ordinance by the Minister of Health.

Art. 143. (1) The medical establishments of art. 142, para 1, shall inform every month the National genetic laboratory about the conducted genetic investigations and the results from them.

(2) The medical establishments of para 1 shall create and maintain official register of the investigations, implemented by them.

(3) The structure of the laboratories of para 1 shall be provided with regulation, issued by the Minister of Health and their activity as well as the order for registration, preservation, processing and access to information in the register shall be provided with the ordinance of art. 142, para 5.

Art. 144. (1) The genetic laboratories at the medical establishments can create DNA banks for taking and preservation of genetic material for scientific and medical purposes.

(2) The medical establishments of para 1 shall register in 7 days term the DNA banks, created by them, at the Ministry of Health under conditions and by order, determined with the ordinance of art. 142, para 5.

Chapter five. PSYCHIC HEALTH

Section I. Protection of the psychic health

Art. 145. (1) The state, the municipalities and the non government organisations shall organise activities for protection of the psychic health, connected with:

1. ensuring for the persons with psychic disorders accessible and high quality medical care, cares and support, necessary for their life in the family and in the community;
2. protection of the psychic health in the risk groups: children, students, aged people,

persons, accommodated in social establishments, military servicemen, detained and deprived from liberty;

3. active prophylactics of the psychic disorders;
4. support of the public initiatives in the field of the psychic health care;
5. specialised continuing education of the persons, who implement activities for protection of the psychic health;
6. fulfilment of programmes for training in strengthening and protection of the psychic health of the persons, who teach, implement medical activity, social adaptation, organisation and management, protection of public order;
7. scientific applied studies, directed to strengthening of psychic health;
8. public awareness on the problems of psychic health.

(2) The municipalities shall ensure conditions for conducting of psychic - social rehabilitation and for support with financial and material means, including conceding abodes to the persons with psychic disorders.

Art. 146. (1) Persons with psychic disorders, in need of special health care, shall be:

1. mentally ill with established serious disorder of the psychic functions (psychosis or grave personality disorder) or with expressed durable psychic damage as result of psychic disease;
2. person with moderate, grave or deep mental retarding or vascular and senile dementia;
3. persons with other disorders of the psychic functions, difficulties in education and troubles in adaptation, requiring medical help, care and support, in order to live adequately in family and in social environment.

(2) Each person with psychic disorder shall enjoy treatment and care under conditions, equal with the conditions of the patients with other diseases.

Art. 147. (1) Nobody can be subject to medical activities for establishing or treatment of psychic disorder except under conditions and by order, determined with a law.

(2) The assessment of existence of psychic disorder cannot be based on family, professional or other conflicts as well as on data about psychic disorder, suffered in the past.

Art. 148. Basic principles at the treatment of persons with psychic disorders shall be:

1. minimum restriction of the personal freedom and respect of the rights of the patient;
2. reduction of the institutional dependence of the persons with psychic disorders on durable hospital treatment under the condition that this does not contradict with the approved medical standards;
3. creating of wide network of specialised establishments for off hospital psychiatric care and priority of the care in the family and in the social environment;
4. integration and equality of the psychiatric care with the other medical directions;
5. observing of the humanitarian principles and norms at implementing the healing process and social adaptation;
6. stimulation of self-help and mutual help and ensuring active public and professional support for the persons with psychic disorders;

7. specialised training, professional training and re-qualification of the persons with psychic disorders with objective their social adaptation;

8. participation of humanitarian non government organisations in the process of treatment and social adaptation.

Art. 149. (1) The treatment of the persons with psychic disorders shall be implemented by medical establishments for primary or specialised off hospital care, medical establishments for stationary psychiatric care, dispensaries, specialised divisions at the multi-profiled hospitals and homes for medical - social care.

(2) The medical activities, connected with the treatment of persons with psychic disorder, shall include diagnostic investigations, medicamental and instrumental methods of treatment and psychotherapy. The conditions and the way for their conducting shall be determined with an ordinance by the Minister of Health.

(3) The use of surgery methods for change in the morphology of the central nervous system with objective achievement of defined psychic characteristics shall be prohibited.

Art. 150. (1) For patients with established psychic disorders, fallen into status, being direct and immediate danger for their own health or life or for the health and the life of other persons, can be applied measures for temporary physical restriction.

(2) The measures of para 1 shall be applied only as prerequisite for creating conditions for conducting the treatment and they do not substitute the active treatment.

(3) The undertaking of measures for physical restriction shall be ordered by a doctor, who defines the kind of the measure and the term for its application. This term cannot be longer than 6 hours.

(4) The measures of para 1 shall be implemented by staff, trained for this in advance.

(5) The kind of the undertaken measures for physical restriction, the reasons, imposed this, the term for their application, the name of the doctor, who has ordered them and the applied medicamental treatment shall be entered into special book of the medical establishment and in the history of the disease.

(6) The person, towards who have been undertaken measures for physical restriction, must be under constant observation by doctor or nurse.

(7) The order for applying measures for physical restriction shall be provided with ordinance by the Minister of Health together with the Minister of Justice.

Art. 151. (1) The labour therapy of the persons with psychic disorder shall be part of the psycho - social rehabilitation programmes.

(2) At conducting the labour therapy shall be inadmissible any for of exploitation and compulsory character of the labour.

(3) The activities for the organisation of the production, the conditions for exercising labour and the way for payment of remuneration for the work shall be provided with ordinance by the Minister of Health in coordination with the Minister of Labour and Social Policy and the Minister of Finance.

Art. 152. (1) In the specialised institutions for rendering social services to persons with psychic disorders shall be created health offices, in which shall work doctor, medical

officer or nurse.

(2) The health offices shall implement activities for:

1. permanent medical observation;
2. rendering of first medical aid;
3. control over the hygiene status of the persons;
4. current control for observing the hygiene requirements;
5. preparing and maintenance of medical documentation for each person.

Art. 153. (1) The emergency psychiatric care shall be combination of medical rules and activities, which shall be applied towards persons with obvious characteristics of psychic disorder when their behaviour or status represents direct and immediate danger for their own health or life or for the health or the life of other persons.

(2) Emergency psychiatric care shall be rendered by the psychiatric dispensaries, the medical establishments for stationary medical care, the psychiatric divisions of clinics at the multi-profile hospitals and the centres for emergency medical care.

(3) Urgent psychiatric care shall be rendered according to the approved medical standards.

Art. 154. (1) When the status of a person of art. 146, para 1, items 1 and 2 imposes continuation of the treatment after coping with the emergency status the chief of the medical establishment shall take decision the person to be accommodated temporary for treatment for a term not longer than 24 hours, notifying immediately the relatives of the patient about this.

(2) As exception the term of para 1 may be extended one time with not more than 48 hours with permission by the district judge.

(3) At need decision to be taken for conducting of compulsory treatment the chief of the medical establishment shall immediately submit to the court motivated request for this, accompanied by statement about the psychic status of the person, prepared by a psychiatrist.

Section II. Compulsory accommodation and treatment

Art. 155. The persons of art. 146, para 1, items 1 and 2, who due to their disease can commit a crime, which represents danger for their relatives, for the people around, for the society or threatens seriously their health, shall be subject to compulsory accommodation and treatment.

Art. 156. (1) The compulsory accommodation and treatment of the persons of art. 155 shall be decreed with decision by the district court at the present address of the person and in the cases of art. 154 - by the district court at the location of the medical establishment.

(2) The compulsory accommodation and treatment shall be implemented in medical establishments for stationary psychiatric care and psychiatric dispensaries, in psychiatric divisions or clinics of the multi-profile hospitals and in medical establishments for specialised psychiatric off hospital care.

Art. 157. The compulsory accommodation and treatment can be required by the prosecutor and in the cases of art. 154, para 3 - also by the chief of the medical establishment.

Art. 158. (1) The court shall send copies of the request for compulsory accommodation and treatment of the person, which accommodation will be considered. The person can in 7 days term make objection and point out evidences.

(2) The court shall consider the case in open session with the participation of the person in 14 days term after receiving of the request.

(3) When permission is given by the district judge by the order of art. 154, para 2, the court shall consider the case immediately and in this case para 1 shall not be applied. The copies shall be delivered at the court session and the chief of the medical establishment shall ensure the appearance of the person.

(4) The participation of psychiatrist, defender and prosecutor shall be obligatory.

(5) The person, whose accommodation is required, must be interrogated personally and if need occurs, he shall be brought compulsory. When the health status of the person does not allow to appear at the court session the court shall be obliged to acquire immediate impression about his status.

Art. 159. (1) the court shall appoint judicial - psychiatric expertise when it establishes that some of the circumstances of art. 155 exists and after hearing to psychiatrist about the probable existence of psychic disorder of the person. The court shall determine the form of conducting of the expertise - ambulatory or stationary.

(2) The court shall determine the medical establishment and the expert for conducting the expertise as well as the term for implementing it, which cannot be longer than 14 days, and set the following session on the case, which shall be conducted not later than 48 hours after finishing of the expertise.

(3) If the term, defined for implementing the expertise, occurs insufficient, as exception the court may in an open session extent it one time but with not more than 10 days. In this case the court shall postpone with the same term also the set session of para 2.

(4) If the court establishes that the circumstances of art. 155 do not exist or after hearing to psychiatrist existence of psychic disorder of the person does not exist the court shall terminate the case.

Art. 160. (1) The judicial - psychiatric expertises shall be conducted by an order, determined with ordinance by the Minister of Health and the Minister of Justice.

(2) During the conducting of the expertise treatment shall not be conducted except at emergency status or after expressed informed consent by the person.

(3) Simultaneously with the expertise the expert shall give statement about the ability of the person to express informed consent for treatment, propose treatment for the concrete disease and recommend medical establishments where it may be conducted.

Art. 161. (1) The definition of the court for termination of the case or for appointing of the expertise shall be subject to appeal with private appeal or protest in three days term. The appealing shall stop the conducting of the expertise unless the court decrees other.

(2) The regional court shall pronounce in an open session. Not appearing of the

person without good reasons shall not be obstacle for considering the case.

Art. 162. (1) After hearing the person about the conclusion of the judicial - psychiatric expertise the court shall pronounce decision on the case on the basis of the collected evidences.

(2) With the decision the court shall pronounce on the need of compulsory accommodation, determine the medical establishment as well as the existence or the lack of ability of the person to express informed consent. The court shall determine the term of the accommodation and the treatment as well as the form of the treatment - ambulatory or stationary.

(3) When lack of ability of the person is accepted the court shall decree compulsory treatment and appoint a person from the relatives of the ill person, who is to express informed consent for the treatment. Upon conflict of interests or lack of relatives the court shall appoint representative of the municipal health service or a person, defined by the mayor of the municipality at the headquarters of the medical establishment, who is to express informed consent about the treatment of the person.

Art. 163. (1) The decision of the court can be appealed by the interested persons in 7 days term after it is decreed. The regional court shall pronounce in 7 days term decision, which shall not be subject to appeal.

(2) Appeal of the decision for compulsory accommodation and treatment shall stop its fulfilment unless the first or the appellate instance decrees other.

Art. 164. (1) The compulsory treatment shall be terminated with the elapse of the term, for which it has been decreed or with a decision of the district court at the location of the medical establishment.

(2) At each quarter on the basis of the judicial - psychiatric expertise, presented by the medical establishment, the district court at the location of the establishment shall officially pronounce decision about termination of the compulsory accommodation and treatment or for continuing of the compulsory accommodation and treatment by the order of art. 158, 159, 160 and 161.

(3) Upon falling away of the prerequisites for compulsory accommodation and treatment before the defined term to have elapsed the compulsory accommodation and treatment can be terminated by the court upon request by the person, the prosecutor or the chief of the medical establishment.

Art. 165. (1) As far as in this section special rules are not contained the provisions of the Penal Procedure Code shall be applied.

(2) The decision for compulsory accommodation and treatment, entered into force, as well as the definition of the court for appointing judicial - psychiatric expertise shall be brought to execution by the respective medical establishments if necessary with the cooperation by the bodies of the Ministry of Interior.

Chapter six.

UNCONVENTIONAL METHODS FOR FAVOURABLE IMPACT ON THE INDIVIDUAL HEALTH

Art. 166. (1) The Minister of Health shall control the applying of the unconventional methods for favourable impact on the individual health, which include:

1. using of non medicine products of organic origin;
2. using of non medicine products of mineral origin;
3. using of not traditional physical methods;
4. homeopathy;
5. acupuncture and acupressure;
6. iris, pulse and auricular methods of investigation;
7. diets and healing hunger.

(2) The use of unconventional methods for favourable impact on the individual health out of these, pointed out in para 1, shall be prohibited.

(3) The Minister of Health shall determine with an ordinance requirements to the activity of the persons, who exercise unconventional methods for favourable impact on the individual health.

Art. 167. (1) Right to practice unconventional methods of art. 166, para 1, except homeopathy, shall have Bulgarian citizens, who are psychically healthy, have not been sentenced for unqualified crimes and meet one of the following conditions:

1. have educational - qualification degree "master" in professional directions "Medicine", "Stomatology" or "Pharmacy";
2. (amend. SG 85/05) have educational - qualification degree "specialist" or "bachelor" in professional direction "Health care";
3. have diploma for graduated high school and certificate for successfully conducted education not less than 4 semesters in a higher medical school under conditions and by order, determined with an ordinance by the Minister of Health and the Minister of Education and Science.

(2) Right to practice homeopathy shall have Bulgarian citizens, who have educational - qualification degree "master" in professional directions "Medicine" or "Stomatology".

Art. 168. The persons, who practice unconventional methods, shall be obliged:

1. to exercise their activity in good faith;
2. not to admit damaging of the health of the persons, who have required their help;
3. to clarify to the persons, required their help, in details and in accessible language what unconventional method they will apply and the expected result from this;
4. to receive the explicit written consent of the persons, required their help, for applying of the respective methods;
5. not to lead into error the persons, who have required their help, including regarding to the possibilities for influence of their health status by the practiced unconventional method.

Art. 169. All forms of advertising of unconventional methods, including their connection with activities for prophylactics, diagnostics, treatment and rehabilitation, shall be

prohibited.

Art. 170. (1) The persons, who practice unconventional methods, shall be registered at the RHC in the region where they practice by submitting application, to which shall be attached documents, certifying the requirements of art. 167.

(2) In the application shall be pointed out comprehensively the unconventional methods and means, which the person will practice.

(3) Upon incompleteness of the presented documents or incompliance with the requirements for registration the director of RHC shall in 15 days term notify in writing the persons about this and determine 10 days term for removing them.

(4) In 15 days term after submitting of the application or removal of the incompleteness the director of RHC shall issue certificate for registration, in which shall be pointed out the kinds of unconventional methods, which the person will apply, or make motivated refusal for issuing it.

(5) The director of RHC can refuse registration if the unconventional method, described in the application, is in violation of the normative requirements.

(6) The refusal of registration shall be subject to appeal by the order of the Law of the administrative procedures.

(7) For implementing the registration fee shall be paid, determined with a tariff, approved by the Council of Ministers.

Art. 171. (1) The Regional health centre shall create and maintain register of the persons, who practice unconventional methods. The register shall be public and it shall contain:

1. consecutive number;
2. date of issuing of the certificate for registration of the unconventional practice;
3. data about the person, who practices unconventional methods - name, unified civil number and permanent address;
4. description of the unconventional method, which the person is practicing;
5. registration number of the book for visits of art. 173;
6. date of deleting of the registration and the ground for this;
7. changes in the circumstances of items 1 - 6;
8. notes of the entered circumstances.

(2) The registered persons shall be obliged to notify the respective RHC about all changes in the implemented registration of the unconventional practice in 7 days term after their occurrence.

Art. 172. (1) The registration shall be deleted:

1. upon request by the person, registered the unconventional practice;
2. upon death of the registered person or his placing under interdict;
3. at established presenting of incorrect data in the documents of art. 170, para 1;
4. at implementing activities in violation of the implemented registration;
5. at establishing unfavourable consequences for human health as result of the applied unconventional methods by the registered person.

(2) The deletion of the registration shall be implemented with order by the director of

RHC.

(3) The orders of para 1, items 3, 4 and 5 shall be subject to appeal by the order of the Law of the administrative procedures.

(4) The appealing of the order shall not stop its fulfilment.

Art. 173. (1) each person, who practices unconventional methods, shall be obliged to enter in the book for visits the data about each person, required his help as follows:

1. date of each visit;
2. consecutive number of each visit;
3. the three names, unified civil number and permanent address;
4. complaints, reported during the visit;
5. the implemented unconventional activities.

(2) The book for visits shall be threaded through, sealed and registered by RHC, issued the registration.

(3) The persons, who practice unconventional methods, shall be obliged to preserve the book for visits for 10 years after its finishing as well as to present it upon request by the control bodies.

Chapter seven.

MEDICAL EDUCATION, MEDICAL PROFESSION, MEDICAL SCIENTIFIC INVESTIGATIONS OF PEOPLE. MEDICAL SCIENCE

Section I.

Medical education

Art. 174. (1) The medical education shall ensure and guarantee the amount and the quality of preparation of the medical specialists, as well as of the non medical specialists, working in the national system for health care.

(2) Basic principles at conducting of the medical education shall be:

1. duration and high quality of teaching with learning of guaranteed amount of theoretic knowledge and practical skills;
2. staging and continuity of the training;
3. right to choice of speciality.

Art. 175. (1) The training and the acquisition of educational - qualification stage "master" in specialities from professional directions "Medicine", "Stomatology", "Pharmacy" and "Public health" shall be organised and conducted in faculties of higher schools, received accreditation by the order of the Law of the higher education.

(2) (amend. SG 85/05) The training and the acquisition of educational - qualification stage "bachelor" in specialities from professional direction "Health care" and in the specialties "nurse" and "midwife" of professional direction "Health care" shall be organised and conducted in faculties and/or branches of higher schools, received accreditation by the order of the Law of the higher education.

(3) (amend. SG 85/05) The training and the acquisition of educational - qualification degree "specialist" in specialities from professional directions "Health care" shall be organised and conducted in colleges, received accreditation by the order of the Law of the higher education. The training in the educational – qualification degree "specialist" shall not be implemented in the specialties "nurse" and "midwife".

(4) The training of persons for acquisition of educational and scientific degree "doctor" in scientific specialities in the field of health care shall be implemented in higher schools, the Bulgarian academy of science, the national centres on the problems of public health and other scientific organisations, received accreditation by the order of the Law of the higher education.

Art. 176. (1) At handing over the diplomas all doctors and stomatologists shall take Hippocratic oath. The text of the oath shall be approved by the Supreme medical council.

(2) (suppl. SG 85/05) For the persons, who are citizens of the European Union, the other states of the European economic space and Switzerland, shall be ensured oath appropriate in content and form.

Art. 177. (suppl. SG 85/05) The Council of Ministers shall approve unified state requirements for acquiring higher education in the specialities of the regulated professions from professional directions "Medicine", "Stomatology", "Pharmacy", "Public health" and "Health care" upon proposal by the Minister of Health.

Art. 178. (1) The post graduate education shall be right of all persons with educational - qualification degree "doctor", "master", "bachelor" and "specialist", who work in the national system for health care.

(2) The post graduate education shall include:

1. training for acquiring speciality in health care;

2. (suppl. SG 85/05) continuing medical training.

(3) The Minister of Health shall every year determine the number of the places for post graduate training in specialities, subsidies by the state in compliance with the objectives and the priorities of the national health strategy.

Art. 179. The Minister of Health shall plan and coordinate the activities for conducting post graduate training for acquiring speciality by the medical specialists with not medical education, working in the national system for health care.

Art. 180. (1) The theoretic training of art. 178, para 2, item 1 shall be conducted by:

1. higher schools, received positive accreditation assessment under the Law of the higher education, and the Military medical academy;

2. national centres on the problems of public health, received accreditation for the respective speciality by the order of the Law of the higher education.

(2) The practical education of art. 178, para 2, item 1 shall be conducted in:

1. the establishments of para 1;

2. medical establishments, received positive accreditation assessment for training of

students and specialising persons.

(3) Speciality shall be acquired after fulfilment of study programmes and successfully passed practical and theoretic examination before state examination commission, determined with an order by the Minister of Health.

Art. 181. (1) The nomenclature of the basic and the profile specialities in the system of health care, the conditions and the order for conducting of the training and acquiring of speciality in health care, as well as its financing, shall be determined with an ordinance by the Minister of Health, coordinated with the Minister of Education and Science and the Minister of Finance.

(2) The financing of the training for acquiring of speciality in health care shall be determined in compliance with the objectives and the priorities of the national health strategy.

Art. 182. (1) (amend. SG 85/05) The professional organisations of the physicians, of the dental doctors and of the nurses, the midwives and the associated medical specialists shall organise, coordinate, conduct and register the continuing medical training of the physicians, the dental doctors and the nurses, the midwives and the associated medical specialists under conditions and by order, determined in contracts with the higher schools, the Bulgarian Red Cross and the Military medical academy.

(2) (amend. SG 85/05) The higher schools, the Military medical academy, the medical colleges, the Bulgarian red Cross and other associations of working in health care shall conduct the continuing medical training of the specialists in the system of health care out of these, pointed out in para 1, under conditions and by order, determined in contracts with the bases for post graduate training.

(3) (amend. SG 85/05) The Union of the scientific medical associations in Bulgaria, the Union of the scientists in Bulgaria and the medical associations in specialities can participate in the conducting of the continuing medical training of doctors and stomatologists under conditions and by order, determined in contracts with the Bulgarian union of doctors and the Union of the stomatologists in Bulgaria.

(4) The control of the activities of para 1 - 3 shall be implemented by order, determined by the Minister of Health.

Section II. Medical profession

Art. 183. (1) (amend. SG 85/05) The medical profession shall be exercised by persons having diploma for graduated higher education in specialties of professional directions "Medicine", "Stomatology", "Pharmacy" and "Health care".

(2) (new – SG 85/05) The diploma of para 1 shall certify the acquired higher education in the respective specialty and educational – qualification degree as well as the acquired professional qualification determined in the state requirements of art. 177.

(3) (prev. (2) – SG 85/05) The doctors and the stomatologists shall exercise the medical profession under the conditions of para 1 and art. 3, para 1 of the Law of the professional organisations of the doctors and the stomatologists.

(4) (new – SG 85/05) The nurses, the midwives and the associated medical specialists shall exercise the medical profession under the conditions of chapter two of the Law of the professional organization of the nurses, the midwives and the associated medical specialists.

Art. 184. (revoked – SG 85/05)

Art. 185. (1) (amend. SG 85/05) The Ministry of Health shall officially create and maintain public list of the persons graduated higher education in specialties of professional directions "Medicine", "Stomatology", "Pharmacy", "Public health" and "Health care".

(2) (revoked – SG 85/05)

(3) (revoked – SG 85/05)

(2) (prev. (4), amend. SG 85/05) The data from the list shall be accessible for use to all persons under the conditions and by the order of the Law of access to public information.

Art. 186. (amend. SG 85/05) (1) The citizens of member state of the European Union, the other states of the European economic space and Switzerland shall exercise medical profession in the Republic of Bulgaria under the conditions of art. 194, para 1 and 2 and art. 195, para 1 and 2.

(2) The Ministry of Health and the higher schools shall ensure to the persons of para 1 conditions for the acquisition of the necessary language knowledge and professional terminology in Bulgarian language for exercising their profession in the Republic of Bulgaria if necessary and when this is in their interest and in the interest of their patients.

(3) The foreigners out of these of para 1 shall exercise medical profession in the Republic of Bulgaria under the conditions of art. 194, para 3 and 4 and art. 195, para 3 and if they have command of Bulgarian language and professional terminology in Bulgarian language established by order determined with ordinance of the Minister of Education and Science and the Minister of Health.

(4) Out of the cases of para 1 - 3 medical profession may exercise also foreigners, invited for scientific exchange between medical establishments, under conditions and by order, determined with an ordinance by the Minister of Health.

(5) The citizens of para 1 may render one time or temporary medical aid on the territory of the Republic of Bulgaria under conditions and by order determined in the ordinance of para 4.

Art. 187. (revoked – SG 85/05)

Art. 188. (amend. SG 85/05) The Minister of Health shall issue ordinances for the professional competence of the persons, working in the national system for health care, graduated higher education in the specialities "psychology", "kinesitherapy", "biology", "biochemistry", "microbiology" and "molecular biology".

Art. 189. The medical establishments shall obligatory insure the persons, who exercise medical profession in medical establishment, for the damages, which can occur due to guilty non fulfilment of their professional obligations.

Art. 190. (1) The persons, exercising medical profession, shall have right to free actions and decisions according to their professional qualification, the medical standards and the medical ethics.

(2) The medical specialists, as well as the medical establishments, cannot use for their activity commercial advertisement.

Art. 191. (1) (amend. SG 85/05) Medical specialist, who for more than five years has not taken position or has not implemented activity, for which is required medical education, shall lose the right to exercise medical profession.

(2) (new – SG 85/05) the persons with higher medical education who take position or implement activity in the field of public health care shall not lose their right to exercise medical profession upon continuing training and exercising of the profession

(3) (prev. (2), amend. SG 85/05) The persons of para 1 shall restore their rights after sitting for examination under conditions and by order, determined with ordinance of the Minister of Health.

Art. 192. (1) The medical specialists cannot exercise their profession if they suffer from diseases, endangering the health and the life of the patients.

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

(3) In the cases of para 1 the Minister of Health shall issue order, with which deletes the medical specialist from the register of art. 185.

(4) The order of the Minister of Health shall be subject to appeal by the order of the Law of the Supreme Administrative Court.

Art. 193. (1) The Minister of Health can with an order divest the right of a person to exercise medical profession in the Republic of Bulgaria for a term from six months to two years in case of:

1. repeated violation of the approved medical standards;
2. the repeated violation of the principles and the order for implementing the expertise of the ability to work.

(2) The order of para 1 shall be subject to appeal by the order of the Law of the Supreme Administrative Court.

Section III.

Recognising of diplomas, certificates and other evidences for professional qualification

Art. 194. (1) (amend. SG 85/05) medical education for exercising medical profession shall be recognised to a person, who has acquired medical education and/or medical profession in a member state of the European Union, the other states in the European economic space and Switzerland.

(2) (suppl. SG 85/05) The Council of Ministers shall, upon proposal by the Minister of Health and the Minister of Education and Science, approve ordinances for the conditions and the order for recognising of diplomas, certificates and other evidences for professional

qualification in medical profession, issued in member countries of the European Union, the other states in the European economic space and Switzerland.

(3) (amend. SG 85/05) Out of the cases of para 1 medical for exercising medical profession shall be recognised to a person, acquired right to exercise medical profession in a state with which the Republic of Bulgaria has concluded international agreement including clauses for mutual recognising of diplomas, certificates and other evidences for official qualification in medical profession, under the agreed conditions.

(4) (amend. SG 85/05) Out of the cases of para 1 and 3 medical education can be recognised to a foreigner under the conditions of mutuality, established for each concrete case, when the person has diploma, certificate or other evidence for professional qualification, in compliance with the unified state requirements for acquiring higher education and meets the requirements of art. 186.

Art. 195. (1) (suppl. SG 85/05) Speciality in the field of health care, acquired in a member country of the European Union, the other states in the European economic space and Switzerland shall be recognised upon the existence of training, complying with the requirements of the ordinance of art. 181.

(2) (suppl. SG 85/05) The conditions and the order for recognising of speciality in the field of health care, acquired in a member country of the European Union, the other states in the European economic space and Switzerland shall be determined with the ordinances of art. 194, para 2.

(3) Out of the cases of para 1 speciality in the field of health care shall be recognised, acquired in the state, with which the Republic of Bulgaria has concluded international agreement for or including clauses for mutual recognising of diplomas, certificates and other evidences for official qualification for acquired speciality in the field of health care, under the agreed conditions and prerequisites.

Art. 196. Out of the cases of art. 195 speciality in the field of health care can be recognised under the conditions of mutuality, established for each concrete case, when the person has diploma, certificate or other evidence for professional qualification, and meets the requirements of this law.

Section IV.

Medical scientific studies of people. Medical science

Art. 197. (1) The Ministry of Health shall organise and control the conducting of medical scientific studies of people.

(2) Medical scientific study in the sense of this law shall be each experiment on people, which is implemented with objective increase of medical knowledge.

(3) The studied person shall have all rights of a patient.

(4) Medical scientific study shall be implemented upon ensuring of maximum safety for the health of the studied person and preserving the secret of his personal data.

(5) The interests of the studied person shall be more important than the scientific and the financial interests of the investigator at any stage of the medical study.

Art. 198. (1) Medical scientific studies of people shall not be implemented when:

1. they contradict with the law or medical ethics;
2. proofs about their safety have not been presented;
3. proofs about the expected scientific benefits have not been presented;
4. they do not comply with the set scientific objective and the plan for conducting the scientific study;
5. there is increased risk for the health and the life of the studied person.

(2) Medical scientific studies of people shall not be conducted with chemical substances and physical sources of radiation, which can cause changes of the human genome.

(3) Medical scientific studies of people shall not be conducted with products of gene engineering, which may lead to transmitting of new characteristics of the generation.

Art. 199. (1) Medical scientific studies shall be implemented only of persons, who have expressed in writing informed consent after written notification by the chief of the study about the essence, the significance, the scope and the eventual risks of the study.

(2) Consent for participation in medical scientific study shall be given only by legally capable person, who understands the essence, the significance, the scope and the eventual risks of the clinic trial.

(3) The consent shall be given personally in written form. It can be withdrawn at any time.

Art. 200. (1) Medical scientific studies of legally incapable persons shall not be implemented.

(2) When significant benefits for the health are not expected to medical scientific studies shall not be subject:

1. pregnant women and breast nursing women;
2. persons, deprived from liberty;
3. military servicemen at conscript military service.

Art. 201. (1) All persons, with who medical scientific studies are conducted, shall be insured for cases of health damages or death.

(2) The general conditions, the minimum insurance sum, the minimum insurance premium, the order and the term for making the insuring of para 1 shall be determined with an ordinance by the Council of Ministers.

Art. 202. (1) The chief of the medical study shall be doctor or stomatologist with recognised medical speciality and he shall be responsible for the planning and the conducting of the studies.

(2) Medical scientific studies of people shall be conducted only by qualified specialists with higher education in the field of medicine, stomatology, pharmacy, biology, biochemistry.

(3) Medical scientific studies can be conducted by foreign persons only on the basis of contract, coordinated with the Minister of Health.

Art. 203. (1) Medical scientific studies shall be conducted upon positive statement by local commission in ethics, established at the medical or the health establishment or in the scientific organisation, in which medical scientific studies are implemented.

(2) The members of the commission of para 1 shall be determined by the chief of the establishment or the organisation.

(3) Specialists, who participate in the preparation, the organisation and the conducting of the scientific study, cannot participate in the commission of para 1.

(4) The local commission in ethics shall give statement in 30 days term after receiving the request by the chief of the study.

(5) The local commission in ethics shall exercise control over the conducting of the medical scientific studies of people, for which it has expressed positive statement.

Art. 204. At finishing the medical scientific study of people the chief of the study shall in 30 days term inform about this the local commission in ethics.

Art. 205. (1) The medical scientific study can be terminated at any stage of its conducting:

1. upon withdrawal of the consent of the studied person;
2. upon proposal by the chief of the study;
3. upon proposal by the chairman of the local commission in ethics in the medical or health establishment upon proven omissions and breaches in the process of its implementation.

(2) At terminating of the medical scientific study under para 1, items 1 and 2 the chief of the study shall inform in 15 days term the local commission in ethics.

Art. 206. The conditions and the order for conducting the medical scientific studies shall be determined with ordinance by the Minister of Health, coordinated with the Minister of Education and Science.

Art. 207. The Minister of Health shall determine scientific projects within the state scientific priorities in the field of medicine upon proposal by the rectors of the higher schools, the directors of the national centres on the problems of public health, chiefs of scientific organisations and other corporate bodies and upon statement by the Supreme medical council.

Art. 208. (1) The Minister of Health shall announce competition for choice of contractors of scientific projects within the defined scientific priorities.

(2) The conditions and the order for conducting the competition and the requirements to the candidates shall be determined with an ordinance by the Minister of Health, coordinated with the Minister of Education and Science.

(3) The scientific projects shall be financed from state subsidies and other sources.

Chapter eight.

ADMINISTRATIVE PUNITIVE PROVISIONS

Art. 209. (1) Who does not appear to obligatory prophylactic medical examination, study or immunisation, shall be punished with fine from 50 to 100 levs and at second not appearing - from 100 to 200 levs.

(2) The penalties of para 1 shall be imposed also to the officials, who have impeded the appearing of the persons for implementing obligatory prophylactic medical examination, study and immunisation.

(3) Parents or guardians, who do not ensure the conducting of the obligatory immunisations of their children, shall be punished with fine from 50 to 100 levs. At second implementing of the breach the fine shall be from 100 to 200 levs.

Art. 210. (1) Who implements activity in violation of the health requirements under this law and the normative acts for its implementation shall be punished with fine from 200 to 5000 levs and at second breach - from 3000 to 10 000 levs.

(2) When the breach of para 1 is implemented by sole entrepreneur, proprietary sanction shall be imposed in extent from 100 to 1500 levs, and at second breach - from 3000 to 9000 levs.

(3) When the breach of para 1 is implemented by corporate body, proprietary sanction shall be imposed in extent from 2000 to 5000 levs, and at second breach - from 6000 to 12 000 levs.

Art. 211. (1) Who implements activity in a site with public designation without having fulfilled his obligation to notify RIPCPH shall be punished with fine from 1000 to 3000 levs and at second breach - from 3000 to 10 000 levs.

(2) When the breach of para 1 is implemented by sole entrepreneur, proprietary sanction shall be imposed in extent from 3000 to 9000 levs, and at second breach - from 9000 to 15 000 levs.

(3) When the breach of para 1 is implemented by corporate body, proprietary sanction shall be imposed in extent from 5000 to 15 000 levs, and at second breach - from 10 000 to 20 000 levs.

Art. 212. (1) Who refuses or impedes the implementing of state health control or taking of samples by the state health control, if he is not subject to graver penalty, shall be punished with fine from 500 to 1000 levs and at second breach - from 1000 to 1500 levs.

(2) Who does not fulfil prescription of the bodies of the state health control, if he is not subject to graver penalty, shall be punished with fine from 500 to 1000 levs and at second breach - from 1000 to 1500 levs.

(3) When the breach of para 1 and 2 is implemented by corporate body or sole entrepreneur, proprietary sanction shall be imposed in extent from 500 to 1000 levs, and at second breach - from 1000 to 1500 levs.

Art. 213. (1) Who does not fulfil order for stopping of sites or parts of them or breaches prohibition for realisation of products and goods, ordered by the bodies of the state health control, if he is not subject to graver penalty, shall be punished with fine from 3000 to 9000 levs and at second breach - from 10 000 to 30 000 levs.

(2) When the breach of para 1 is implemented by sole entrepreneur, proprietary

sanction shall be imposed in extent from 2000 to 6000 levs, and at second breach - from 6000 to 12 000 levs.

(3) When the breach of para 1 is implemented by corporate body, proprietary sanction shall be imposed in extent from 5000 to 15 000 levs, and at second breach - from 15 000 to 30 000 levs.

Art. 214. (1) Who implements activities for destroying or dismantling asbestos and/or asbestos containing materials from buildings, constructions, enterprises, installations or ships without permission, shall be punished with fine up to 1500 levs and at second breach - from 1500 to 3000 levs.

(2) When the breach of para 1 is implemented by sole entrepreneur, proprietary sanction shall be imposed in extent from 500 to 1500 levs, and at second breach - from 1500 to 5000 levs.

(3) When the breach of para 1 is implemented by corporate body, proprietary sanction shall be imposed in extent from 1000 to 3000 levs, and at second breach - from 3000 to 6000 levs.

Art. 215. Ill with infectious disease, pointed out in art. 61, who refuses obligatory isolation and treatment, shall be punished with fine from 50 to 500 levs. The persons, refused to appear voluntary for isolation and treatment, shall be brought compulsory with the cooperation of the bodies of the Ministry of Interior upon request by the chief of the medical establishment for hospital care.

Art. 216. A medical specialist, who breaches the order for registration, announcement and account, as well as the order for isolation, investigation and dispensary system treatment of ill, former ill, infection carriers and contact persons, shall be punished with fine from 300 to 1000 levs and at second breach - with deprivation from the right to exercise medical profession for term from 6 months to one year.

Art. 217. (1) Who implements activities for disinfection, disinsection and deratisation in violation of the established requirements under this law and the normative acts for its implementation, shall be punished with fine from 500 to 1500 levs and at second breach - from 1500 to 3000 levs.

(2) When the breach of para 1 is implemented by sole entrepreneur, proprietary sanction shall be imposed in extent from 300 to 1000 levs, and at second breach - from 1000 to 3000 levs.

(3) When the breach of para 1 is implemented by corporate body, proprietary sanction shall be imposed in extent from 500 to 1500 levs, and at second breach - from 1500 to 5000 levs.

Art. 218. (1) Who breaches art. 54 or art. 56 shall be punished with fine from 50 to 100 levs and at second implementation of the same breach - from 100 to 300 levs.

(2) For breaches of art. 54, implemented corporate bodies, proprietary sanction shall be imposed in extent from 500 to 1500 levs, and at second breach - from 3000 to 10 000 levs.

(3) Who advertises alcohol beverages in breach of art. 55, para 1 and 2 shall be punished with fine from 500 to 1500 levs, and at second breach - from 1500 to 5000 levs.

(4) If the breach of para 3 has been implemented by sole entrepreneur the proprietary sanction shall be from 300 to 1000 levs, and at second breach - from 1000 to 3000 levs.

(5) If the breach of para 3 has been implemented by corporate body the proprietary sanction shall be from 500 to 1500 levs, and at second breach - from 1500 to 5000 levs.

(6) The radio and television operators, who in breach of art. 55, para 1 and 3 transmit advertisement of spirit beverages, shall be punished with proprietary sanction in extent of 5000 levs and at second breach - 10 000 levs, imposed by the Council for electronic media by the order of the Law of radio and television.

(7) The radio and television operators, who in breach of art. 55, para 2 transmit advertisement of spirit beverages, shall be punished by the order of the Law of radio and television.

Art. 219. (1) Who implements activities with sources of ionising radiations in breach of the requirements of this law and the normative acts for its implementation shall be punished with fine from 2000 to 5000 levs and at second breach - from 5000 to 15 000 levs.

(2) When the breach of para 1 is implemented by sole entrepreneur, proprietary sanction shall be imposed in extent from 1000 to 3000 levs, and at second breach - from 3000 to 10 000 levs.

(3) When the breach of para 1 is implemented by corporate body, the proprietary sanction shall be from 1500 to 5000 levs, and at second breach - from 5000 to 15 000 levs.

Art. 220. (1) An official, who does not inform the patient about the circumstances of art. 88, para 1, shall be punished with fine from 300 to 1000 levs and at second breach - with deprivation from the right to exercise medical profession for a term from 6 months to one year.

(2) Who renders medical care without informed consent of the patient or in violation of the requirements for giving informed consent by the patient, shall be punished with fine from 500 to 1500 levs and at second breach - with deprivation from the right to exercise medical profession for a term from 6 months to one year.

(3) An official, who concedes health information out of the conditions and the order of this law and the normative acts for its implementation, if not subject to graver penalty, shall be punished with fine from 500 to 1500 levs and at second breach - from 2000 to 6000 levs.

Art. 221. Who violates rights of a patient, regulated with this law and with the normative acts for its implementation, shall be punished with fine from 300 to 1000 levs and at second breach - from 500 to 1500 levs.

Art. 222. (1) (amend. SG 85/05) Who renders medical care or implements health activity without having the necessary medical education for this, if he is not subject to a graver penalty, shall be punished with fine from 5000 to 10 000 levs and at second breach - from 10 000 to 20 000 levs.

(2) Medical specialist, who admits systematic breaches at exercising his profession due to negligence or ignorance, admits gross errors in his work or commits immoral acts by using his official status, if he is not subject to a graver penalty, shall be punished with

deprivation from right to exercise his profession for a term from three months to two years.

(3) Doctor, stomatologist, nurse, midwife and medical officer, who refuses rendering of emergency medical aid to a person in status, critical for his life, shall be punished with fine from 1000 to 5000 levs, and at second breach - with deprivation from the right to exercise his profession for a term from three months to one year.

Art. 223. Who implements assisted reproduction in violation of chapter four, section III, if not subject to graver penalty, shall be punished with fine from 15 000 to 50 000 levs and at second breach - with deprivation from the right to exercise his profession for a term from three months to one year.

Art. 224. An official, who imposes measures for physical restriction of a patient with established psychic disorder in violation of the requirements of this law and the normative acts for its implementation, if not subject to graver penalty, shall be punished with fine from 500 to 1500 levs and at second breach - with deprivation from the right to exercise his profession for a term from three months to one year.

Art. 225. (1) Medical specialist, who issues patent's card in violation of the normatively established requirements, shall be punished with fine from 1000 to 3000 levs and at second breach - from 4000 to 10 000 levs.

(2) An official, who does not fulfil the order of the director of the regional health centre for establishing medical consultative commission, shall be punished with fine from 500 to 1500 levs and at second breach - from 1500 to 4500 levs.

Art. 226. Who implements medical scientific study in violation of this law, if not subject to graver penalty, shall be punished with fine from 2000 to 6000 levs and at second breach - with deprivation from the right to exercise his profession for a term from three months to one year.

Art. 227. Who practices unconventional methods for impact on individual health in violation of this law and the normative acts for its implementation shall be punished with fine from 500 to 1500 levs and at second breach - from 1500 to 5000 levs.

Art. 228. Medical specialist, who violates the requirements, established with this law and with the normative act for its implementation, to the form, the content, the conditions and the order for use, processing, analysis, preservation and conceding of the medical documentation, shall be punished with fine from 500 to 1500 levs and at second breach - from 1500 to 3000 levs.

Art. 229. (1) Who violates the provisions of this law or the normative act for its implementation out of the cases of art. 209 - 228, shall be punished with fine from 200 to 600 levs and at second implementation of the same breach - from 1000 to 3000 levs.

(2) When the breach of para 1 is implemented by sole entrepreneur, proprietary

sanction shall be imposed in extent from 200 to 600 levs, and at second breach - from 600 to 2000 levs.

(3) When the breach of para 1 is implemented by corporate body, proprietary sanction shall be imposed in extent from 500 to 2000 levs, and at second breach - from 2000 to 5000 levs.

Art. 230. (1) The violations of art. 225 and 227 shall be established with acts, compiled by officials, determined by the director of RHC and the punitive decrees shall be issued by the director of RHC.

(2) Copy of the punitive decree, issued for breaches of para 1 shall be sent to the higher body for expertise of the ability to work, to the regional council for control over the acts, issued by the bodies for expertise of the temporary inability to work, to the persons, interested in the expertise (the certified, the insurers and the National Insurance Institute) and to RHIF.

Art. 231. The violations of art. 210 - 217 and art. 218, para 1, 2, 3, 4 and 5 shall be established with acts, compiled by state health inspectors and the punitive decrees shall be issued by the director of RIPCPh.

Art. 232. The violations of art. 209, 215 and 218 shall be established with acts, compiled by officials, determined by the director of RHC or state health inspectors and the punitive decrees shall be issued respectively by the director of RHC or by the director of RIPCPh.

Art. 233. The violations of art. 219 shall be established with acts, compiled by state health inspectors or officials, determined by the director of NCRRP and the punitive decrees shall be issued by the director of the respective RIPCPh or by the director of NCRRP.

Art. 234. The violations of art. 220 - 228 shall be established with acts, compiled by officials, authorised by the Minister of Health or the director of RHC and the punitive decrees shall be issued by the Minister of Health or an official, authorised by him or by the director of RHC.

Art. 235. The violations of art. 229 shall be established with acts, compiled by officials, authorised by the Minister of Health or by the director of RHC, or by state health inspectors, and the punitive decrees shall be issued according to the conceded competence - by the Minister of Health, by the director of RHC or by the director of RIPCPh.

Art. 236. The compiling of the acts, the issuing, the appealing and the execution of the punitive decrees shall be implemented according to the provisions of the Law of the administrative offences and sanctions.

Additional provisions

§ 1. In the sense of this law:

1. "Health documentation" are all forms for registration and preservation of health information.

2. "Dispensary system" is method of active search, diagnostics, treatment and periodic observation of ill persons with defined diseases.

3. "Invasive methods" are diagnostic and treatment instrumental methods, at which through by invading the entity of the skin and the mucosa or through natural openings is penetrated into human body.

4. "Medical - legal procedures" are procedures, implemented with objective protection of the security of the country, the internal order or the health of the citizens without medical indication.

5. "Second breach" is breach, implemented in one year term after the entering into force of the punitive decree, with which the offender is punished for breach of the same kind.

6. "Screening" is purposed prophylactic study, implemented according to defined programme for establishing the dissemination of defined characteristic, symptom or disease among a group of individuals.

7. "Physical restriction" is applying of mechanical means for immobilisation, compulsory isolation in a special closed premises and use of medical products for reduction of the physical activity of the patient in cases when he is dangerous for himself or for those around.

8. "Promotion of health" is a process at which by ensuring social, economic, ecological and other conditions and adequate health education is given opportunity to the individuals to improve their health by strengthening the personal and the group responsibility.

9. "Sites of public designation" are:

a) water sources and mineral water sources, water supply sites, facilities and networks for drinking - household water supply;

b) swimming pools, beaches and places for bathing;

c) (amend. SG 94/05) means for shelter - hotels, motels, villa and tourist settlements, and places for accommodation - boarding houses, rest homes, family hotels, independent rooms, villas, houses, bungalows, camping places as well as tourist cottages – tourist cottages, tourist training centers and tourist boarding houses;

d) sport sites - stadiums, sport halls, playgrounds, fitness centres and halls;

e) theatres, cinemas, concert halls, computer and Internet halls, gambling halls;

f) barber's, hairdresser's and cosmetic parlours, public baths, laundries, saunas, public toilettes;

g) graveyard parks;

h) enterprises for production and wholesale trade with medicines, pharmacies, drugstores;

i) enterprises for production, preservation and trade with cosmetics;

j) railway stations, airports, ports, bus stations, metro-stations;

k) fuel stations, gas stations;

l) transport vehicles for public transport - trains, aircraft, ships, buses, trams, trolley-buses, metro-trains, transport vehicles with special designation - sanitary automobiles for ill persons, medicines and consumables, automobiles for transport of food, automobiles for transport of body remains;

m) (suppl. SG 94/05) enterprises for production, preservation and trade with foods, catering and entertainment establishments as well as catering establishments adjacent to tourist

cottages – tourist canteens, tourist buffets and tourist canteens with waiter servicing;

n) creches and kindergartens and establishments for social services for children and students, schools and higher schools, student hostels, schools for music, languages, sports and centres for work with children;

o) medical and health establishments, services for labour medicine;

p) enterprises for disinfection and deratisation;

q) sites with sources of ionising radiations;

r) sites for production, preservation and trade with chemical substances, preparations and products;

s) agricultural pharmacies.

10. "Products and goods of importance for human health" are:

a) foods, food additives, materials and subjects, designated for contact with foods;

b) medicines;

c) cosmetic products;

d) chemical substances, preparations and products;

e) second hand clothes.

11. "Activities of importance for human health" are:

a) development of the urbanised territories;

b) designing, construction, reconstruction, expansion, entering into exploitation of residential buildings and sites with public designation;

c) maintaining of the hygiene of the settlements by the municipalities;

d) fulfilment of the immunisation calendar of the Republic of Bulgaria;

e) not admitting and restriction of inter-hospital infections in the medical establishments;

f) implementing disinfection, disinsection and deratisation;

g) preparing and observing of the weekly study schedules;

h) observing of the physiological norms for organised catering of groups of the population.

12. "The factors of the living environment" are:"

a) waters, designated for drinking - household needs;

b) waters, designated for bathing;

c) mineral waters, designated for drinking or for use for prophylactic, treatment or for hygiene needs;

d) noise and vibrations in residential, public buildings and urbanised territories;

e) ionising radiations in the residential, the production and the public buildings;

f) non ionising radiations in the residential, the production and the public buildings;

g) chemical factors and biological agents in the sites with public designation;

h) resort resources;

i) air.

13. "Urbanised territories" are the settlements and the settlement formations within construction boundaries, determined with a development plan.

14. "Cosmetic product" is each substance or preparation, designated for contact with the different external parts of human body - skin (epidermis), hair, nails, lips and external sexual organs, or with the teeth and the mucosa (mucous membrane) of the oral cavity, exclusively or primarily with objective their cleaning, perfuming, change of the appearance and/or correction of the odours and/or protection and maintaining in good status.

15. "Informed consent" is consent, given voluntary after acquainting with defined

information.

16. "Reproduction health" is the health of the persons, connected with their abilities to create generation.

17. "Alcohol beverages" are the spirit beverages, wine and beer.

18. "Spirit beverages" are liquids, designated for consumption, containing at least 15 volume percent ethyl alcohol.

19. "Direct advertisement" is each form of commercial message, note or recommendation, aiming promotion of alcohol beverages and/or their consumption by using the beverages themselves or activities, connected with their consumption, production and distribution.

20. "Indirect advertisement" is each form of commercial message, note, recommendation or activity, using name or manufacturer's name of alcohol beverage, as well as name or manufacturer's name of producer of alcohol beverages on products and goods, which are not alcohol beverages.

21. "Assisted reproduction" is diagnostic and treatment methods, by which is aimed overcoming of sterility and which are implemented in specialised centres.

22. "Dietetics" is treatment method at which by prescribed nutrition regime, including only with fruits, vegetables or other products of organic origin, is achieved favourable impact on the individual health.

23. "Healing hunger" is treatment method at which by prescribed regime of taking in water, juices and other liquids is achieved favourable impact on the individual health.

Transitional and concluding provisions

§ 2. (1) The persons, who have right to exercise medical profession by the order of the revoked Law of the public health, shall be legally capable medical specialists in the sense of art. 184.

(2) The Minister of Health shall determine with an ordinance the order for entering of the persons of para 2 in the register of art. 185.

§ 2a. (new – SG 76/05) (1) The persons who have acquired educational – qualification degree "master" in professional direction "Stomatology" shall have the rights of persons acquired education – qualification degree "master" in "Dental medicine".

(2) The Minister of Health shall issue document with which he certifies the rights of the persons of para 1.

§ 3. The persons, to whom till December 31, 2004 is determined degree of durably reduced ability to work, at rounding 65 years of age shall be considered with determined degree of durably reduced ability to work for life.

§ 4. (1) In one month term after the law enters into force the Council of Ministers shall transform the existing district health centres into regional health centres and the existing hygiene - epidemiological inspectorates - into regional inspectorates for protection and control of public health.

(2) The Minister of Health shall in one month term after the decree of para 1 enters into force issue Regulation for the structure and the activity of the regional health centres and Regulation for the structure and the activity of the regional inspectorates for protection and control of public health.

(3) The persons, who exercise state sanitary control in the hygiene - epidemiological inspectorates by the entering of this law in force, shall have the rights of § 3 of the transitional and concluding provisions of the Law of the civil servant.

(4) The regional inspectorates for preservation and control of public health can conclude contracts with the NHIF till December 1, 2005.

§ 5. This law shall revoke the Law of the public health (Prom. SG. 88/73, corr. SG. 92/73, amend. SG. 63/76, amend. SG. 28/83, amend. SG. 66/85, amend. SG. 27/86, amend. SG. 89/88, amend. SG. 87/89, amend. SG. 99/89, amend. SG. 15/91, corr. SG. 24/91, amend. SG. 64/93, amend. SG. 31/94, amend. SG. 36/95, amend. SG. 12/97, amend. SG. 87/97, amend. SG. 124/97, suppl. SG. 21/98, amend. SG. 7098, amend. SG. 71/98, amend. SG. 93/98, amend. SG. 30/99, amend. SG. 62/99, amend. SG. 67/99, amend. SG. 90/99, suppl. SG. 113/99, amend. SG. 10/00, amend. SG. 36/00, amend. SG. 63/02, amend. SG. 83/03, suppl. SG. 102/03).

§ 6. In art. 52, para of the Law of the automobile transport (prom. SG 82/99, amend. SG11, 45/02,SG 99/03) the words "the sanitary" shall be substituted by "the bodies for state health control".

§ 7. In the Law of safe use of nuclear energy (prom. SG 63/02, amend. SG 120/02) the following amendments and supplements shall be made:

1. In art. 15:

a) in para 3 item 6 shall be revoked;

b) in para 4 item 8 shall be revoked;

2. In art. 18, para 1, item 3 shall be changed to:

"3. of art. 15, para 3, items 2 - 5 in term up to one month".

3. In art. 29:

a) the previous text shall become para 1;

b) para 2 shall be created:

"(2) Fee shall not be due for issuing of permission for import or export of sources of ionising radiations or parts of them."

4. In art. 31:

a) new para 2 shall be created:

"(2) The initial license fee for issuing license for use of radioactive substances and other sources of ionising radiations for medical objectives and the annual license fees shall be in extent of 50 percent of the fees, determined under art. 28, para 1.";

b) the previous para 2 shall become para 3.

5. In art. 57 item 1 shall be revoked.

6. In art. 58:

a) in para 1 item 5 shall be revoked;

b) in para 3 after the words "for term" shall be added "of three".

7. Art. 59 shall be changed to:

"Art. 59. Permission for import of radioactive sources of ionising radiations shall be issued if:

1. the person, for whom they are designated, has the necessary license or permission, giving to him right to use and/or preserve them;

2. is ensured their transport by a person, who has license or permission for transport under this law."

8. In art. 60:

a) in para 2 the words "and/or the national consultants in radiation therapy, nuclear medicine and radiology" shall be deleted;

b) para 3 shall be created:

"(3) The official coordination of para 2 shall be implemented with obligation that the sources of ionising radiations can be used for medical purposes."

9. Art. 61 shall be revoked.

10. In art. 63 after the words "The licensee" shall be added "or the titular of permission".

§ 8. In art. 47, para 1 of the Law of the higher education (Prom. SG. 112/95, amend. SG. 28/96, amend. SG. 56/97, corr. SG. 57/97, amend. SG. 58/97, amend. SG. 60/99, corr. SG. 66/99, amend. SG. 111/99, amend. SG. 113/99, amend. SG. 54/00, amend. SG. 22/01, amend. SG. 40/02, amend. SG. 53/02, amend. SG. 48/) after the words "agrarian sciences" shall be added "the national centres on the problems of public health".

§ 9. In the Law of the waters (Prom. SG. 67/99, amend. SG. 81/00, amend. SG. 34/01, amend. SG. 41/01, amend. SG. 108/01, amend. SG. 47/02, amend. SG. 74/02, amend. SG. 91/02, amend. SG. 42/03, amend. SG. 69/03, amend. SG. 84/03, suppl. SG. 107/03) the following amendments and supplements shall be made:

1. In art. 42, first sentence the word "sanitary" shall be substituted by "hygiene - epidemiological".

2. In art. 47, para 2 the words "the public health establishments" shall be substituted by "the medical establishments for hospital care".

3. In art. 48, para 1, item 7 the word "sanitary" shall be substituted by "hygiene - epidemiological".

4. In art. 151, item 1 f) the words "the public health establishments" shall be substituted by "the medical establishments for hospital care".

§ 10. Everywhere in the Law of the civil registration (prom. SG 67/99, amend. SG 28, 37/01, SG 54/02, SH 63/03) the words "health establishment" and "specialised health establishments" shall be substituted respectively by "medical establishment" and "medical establishments".

§ 11. In the Law of the civil aviation (Prom. SG. 94/72, amend. SG. 30/90, amend. SG. 16/97, amend. SG. 85/98, amend. SG. 12/00, amend. SG. 34/01, amend. SG. 111/01, amend. SG. 52/04) the following changes shall be made:

1. In art. 71, para 1 a) the words "health establishment" shall be substituted by

"medical establishment".

2. In art. 85, para 2 the words "the sanitary" shall be substituted by "the medical".

§ 12. In art. 40, para 1 of the Law of value added tax (Prom. SG. 153/98, corr. SG. 1/99, suppl. SG. 44/99, amend. SG. 62/99, suppl. SG. 64/99, amend. SG. 103/99, amend. SG. 111/99, suppl. SG. 63/00, suppl. SG. 78/00, amend. SG. 102/00, amend. SG. 109/01, amend. SG. 28/02, amend. SG. 45/02, amend. SG. 117/02, suppl. SG. 37/03, amend. SG. 42/03, amend. SG. 86/03, amend. SG. 109/03, amend. SG. 53/04) the words "health establishments under the Law of public health" shall be substituted by "national centres on the problems of public health" and the words "medical specialists under the Law of public health" shall be substituted by "medical specialists under the Law of health".

§ 13. In art. 123, para 1, item 2 d) of the Law of movement on roads (prom. SG 20/99, amend. SG 1/00, SG 43, 45, 76/02, SG 16, 22/03, SG 6/04) the words "the health establishment" shall be substituted by "the medical establishment".

§ 14. In art. 83, para 4 of the Law of railway transport (prom. SG 97/00, amend. SG 47, 96/02) the words "the sanitary" shall be substituted by "the bodies for state health control".

§ 15. In art. 32, item 8 of the Law of protection of child (prom. SG 48/00, amend. SG 75, 120/02, SG 36, 63/03) the words "from diseases of art. 36 and 36a of the Law of public health" shall be substituted by "from AIDS and diseases of art. 61, para 1 and art. 146, para 1, items 1 and 2 of the Law of health".

§ 16. In art. 37, para 2, item 2 of the Law of exchange of the military obligations with alternative service (prom. SG 131/98, amend. SG 69/99, SG 49/00, SG 50/03) the words "bodies of the state sanitary control" shall be substituted by "bodies for state health control".

§ 17. In the Law of health insurance (Prom. SG. 70/98, amend. SG. 93/98, amend. SG. 153/98, amend. SG. 62/99, amend. SG. 65/99, amend. SG. 67/99, amend. SG. 69/99, amend. SG. 110/99, amend. SG. 113/99, amend. SG. 1/00, amend. SG. 64/00, suppl. SG. 41/01, amend. SG. 1/02, amend. SG. 54/02, amend. SG. 74/02, amend. SG. 107/02, amend. SG. 112/02, amend. SG. 119/02, amend. SG. 120/02, amend. SG. 8/03, suppl. SG. 50/03, amend. SG. 107/03, suppl. SG. 114/03, amend. SG. 28/04, suppl. SG. 38/04, amend. SG. 49/04) the following amendments and supplements shall be made:

1. In art. 49 the words "the state sanitary control" shall be substituted by "the state health control".

2. In art. 58 the words "and health establishments under the Law of public health" shall be substituted by "national centres on the problems of public health under the Law of health".

§ 18. In the Law of healthy and safe labour conditions (prom. SG 124/97, amend. SG 86/99, SG 64, 92/00, SG 25, 111/01, SG 18, 114/03) the following amendments and

supplements shall be made:

1. In art. 25 para 6 shall be created:

"(6) The activities of the services for labour medicine shall be subject to accreditation under the conditions and by the order, determined for accreditation of the medical establishments with the Law of the medical establishments."

2. In art. 37, item 6 the word "sanitary" shall be substituted by "health".

§ 19. In art. 9 of the Law of execution of penalties (Prom. SG. 30/69, amend. SG. 34/74, amend. SG. 84/77, amend. SG. 36/79, amend. SG. 28/82, amend. SG. 27/86, amend. SG. 89/86, amend. SG. 26/88, amend. SG. 21/90, amend. SG. 109/93, amend. SG. 50/95, amend. SG. 12/97, suppl. SG. 13/97, amend. SG. 73/98, amend. SG. 153/98, amend. SG. 49/00, amend. SG. 62/02, amend. SG. 120/02, amend. SG. 61/04, amend. SG. 66/04) the words "the sanitary requirements" shall be substituted by "the health requirements".

§ 20. In the Law of blood, blood donation and blood transfusion (SG 102/03) the following amendments and supplements shall be made:

1. Art. 34a shall be created:

"Art. 34a. (1) All medical establishments for hospital care and dispensaries with beds can take blood for auto-blood-transfusion observing the requirements of art. 12, para 2 when they have no medical counterindications for this and after receiving written informed consent.

(2) When the person is under age written informed consent shall be taken from the lawful representative or tutor of the under-aged."

2. In the additional provision item 13 shall be created:

"13. Auto-blood-transfusion" is method at which to a patient is transfused blood, which has been taken in advance from him."

§ 21. In the Law of the medicines and the pharmacies in humanitarian medicine (Prom. SG. 36/95, amend. SG. 61/96, amend. SG. 38/98, amend. SG. 30/99, amend. SG. 10/00, amend. SG. 37/00, amend. SG. 59/00, amend. SG. 78/00, amend. SG. 41/01, amend. SG. 107/02, amend. SG. 120/02, corr. SG. 2/03, amend. SG. 56/03, amend. SG. 71/03, amend. SG. 112/03) everywhere the words "the chief state sanitary inspector" shall be substituted by "the chief state health inspector" and the words "hygiene - epidemiological inspectorate" and "hygiene - epidemiological inspectorates" shall be substituted respectively by "the regional inspectorate for protection and control of public health" and "the regional inspectorates for protection and control of public health".

§ 22. In the Law of the medical establishments (Prom. SG. 62/99, suppl. SG. 88/99, amend. SG. 113/99, corr. SG. 114/99, amend. SG. 36/00, amend. SG. 65/00, amend. SG. 108/00, amend. SG. 51/01, amend. SG. 62/01, amend. SG. 28/02, amend. SG. 83/03, amend. SG. 102/03, amend. SG. 114/03) the following amendments and supplements shall be made:

1. In art. 86:

a) new para 2 shall be created:

"(2) The medical establishments, out of these, pointed out in para 1, shall be subject to voluntary accreditation for assessment of their basic capabilities for training of students and specialising persons and doctors for the objectives of the continuing medical education.";

b) the previous para 2 shall become para 3.

2. Art. 91 shall be changed to:

"Art. 91. In the medical establishments for off hospital care can be conducted practical training of specialising persons in specialities, determined with the ordinances of art. 181 of the Law of health, and training for the objectives of the continuing medical education."

3. In art. 115 the following amendments shall be made:

a) in para 1 the words "100 to 300 levs" shall be substituted by "1000 to 3000 levs";

b) new para 2 shall be created:

"(2) Who implements activity for off hospital medical care in violation of art. 39 shall be punished with fine in extent from 2000 to 5000 levs and at second breach - with deprivation from the right to exercise his profession for a term from three months to one year";

c) the previous para 2 shall become para 3 and in it the words "200 to 500 levs" shall be substituted by "2000 to 5000 levs".

4. I art. 116:

a) in para 1 the words "100 to 500 levs" shall be substituted by "1000 to 5000 levs".

b) in para 2 the words "750 to 2000 levs" shall be substituted by "8000 to 20 000 levs".

5. Everywhere in the law the words "district health centre" and "district health centres" shall be substituted respectively by "regional health centre" and "regional health care centres" and the words "the hygiene - epidemiological inspectorate" shall be substituted by "the regional inspectorate for preservation and control of public health".

§ 23. In art. 6. para 1, item c) of the Law of the local taxes and fees (Prom. SG. 117/97, amend. SG. 71/98, amend. SG. 83/98, amend. SG. 105/98, amend. SG. 153/98, amend. SG. 103/99, amend. SG. 34/00, amend. SG. 102/00, amend. SG. 109/01, amend. SG. 28/02, amend. SG. 45/02, amend. SG. 56/02, amend. SG. 119/02, amend. SG. 84/03, amend. SG. 112/03, amend. SG. 6/04, suppl. SG. 18/04, amend. SG. 36/04) after the word "creches" shall be added "children's kitchens".

§ 24. In art. 82 of the Law of the Ministry of Interior (Prom. SG. 122/97, amend. SG. 29/98, amend. SG. 70/98, amend. SG. 73/98, amend. SG. 153/98, amend. SG. 30/99, amend. SG. 110/99, amend. SG. 1/00, amend. SG. 29/00, amend. SG. 28/01, amend. SG. 45/02, amend. SG. 119/02, amend. SG. 17/03, amend. SG. 26/03, amend. SG. 95/03, amend. SG. 103/03, amend. SG. 112/03, amend. SG. 114/03, amend. SG. 15/04) para 3 shall be changed to:

"(3) The establishments for sobering shall be established by the Ministry of Interior in coordination with the municipalities".

§ 25. In the Law of the sea waters, the internal water ways and the ports of the Republic of Bulgaria (Prom. SG. 12/00, amend. SG. 111/01, amend. SG. 24/04) the following amendments shall be made:

1. In art. 23, para 1 the words "the sanitary" shall be substituted by "the health".

2. In art. 38 and in art. 66 the words "the sanitary requirements" shall be substituted by "the health requirements".

§ 26. In art. 19, para 2, item 1 of the Law of the taxation of the income of the physical persons (Prom. SG. 118/97, amend. SG. 35/98, amend. SG. 71/98, amend. SG. 153/98, suppl. SG. 50/99, amend. SG. 103/99, amend. SG. 111/99, amend. SG. 105/00, amend. SG. 110/01, suppl. SG. 40/02, amend. SG. 45/02, suppl. SG. 61/02, amend. SG. 118/02, amend. SG. 42/03, amend. SG. 67/03, suppl. SG. 95/03, amend. SG. 112/03, amend. SG. 36/04, amend. SG. 37/04, amend. SG. 53/04) the words "and the health" shall be deleted.

§ 27. In art. 95 of the Law of the waste management (SG 86/03) the words "the director of the hygiene - epidemiological inspectorate" shall be substituted by "the director of RIPCPH" and the word "sanitary shall be substituted by "health".

§ 28. In the Law of preservation of environment (prom. SG. 91/02, corr. SG. 98/02, amend. SG. 86/03) in chapter three after art. 59 section VIII shall be created with names "Protection of environment against asbestos pollution" with art. 59a:

Section VIII.

Protection of the Environment Against Asbestos Pollution

Art. 59a. (new, SG 70/04) (1) The Minister of Environment and Waters, in coordination with the Minister of Health shall determine by an ordinance:

1. the requirements and the measures for prevention and reduction of the pollution of the air and water with asbestos;
2. the methods and procedures for establishing asbestos in dust emissions;
3. the methods and procedures for determining the concentration of insoluted substances in waste waters containing asbestos;
4. the cases admitting exceptions from the requirements and measures under item 1.

(2) The Minister of Environment and Waters may permit the using of methods and procedures, other than those determined by the ordinance under para 1, if they provide the obtaining of equivalent data and results."

§ 29. In art. 200k of the Law of the judicial power (Prom. SG. 59/94, amend. SG. 78/94, amend. SG. 87/94, amend. SG. 93/95, suppl. SG. 64/96, amend. SG. 96/96, amend. SG. 104/96, amend. SG. 110/96, amend. SG. 58/297, amend. SG. 122/97, amend. SG. 124/97, amend. SG. 11/98, amend. SG. 133/98, amend. SG. 6/99, amend. SG. 34/00, amend. SG. 38/00, suppl. SG. 84/00, amend. SG. 25/01, amend. SG. 74/02, amend. SG. 110/02, amend. SG. 118/02, amend. SG. 61/03, amend. SG. 112/03, amend. SG. 29/04, amend. SG. 36/04) para 3 shall be created:

"(3) With the ordinance of para 2 shall also be determined the conditions and the order for determining and payment of the expenses of the medical establishments at implementing judicial expenses".

§ 30. (amend. SG 76/05) In the Law of the professional organisations of the physicians and the dental doctors (SG 83/98) the following amendments and supplements shall be made:

1. In art. 4 the words "art. 88 and 93 of the Law of public health" shall be substituted

by "chapter seven, section II of the Law of health".

2. In art. 5, item 4 the words "together with the National Health Insurance Fund" shall be deleted.

3. In art. 9 item 9 shall be deleted.

4. In art. 32, para 3:

a) item 2 shall be changed to:

"2. certificate with regard to the law of health;"

b) item 6 shall be changed to:

"6. for foreigners - permission for long term stay and work in the country and certificate for legal capacity under the Law of health."

5. In art. 33, para 1 the words "of art. 88 and 93 of the Law of public health" shall be substituted by "chapter seven, section II of the Law of health".

6. In the transitional and concluding provisions § 6a shall be created:

"§ 6a. The Bulgarian physician's union and the Union of the stomatologists in Bulgaria" shall prepare and approve Rules for good medical practice and propose them for approval to the Minister of Health till July 1, 2005."

§ 31. In art. 4, para 4 of the Law of gambling (Prom. SG. 51/99, amend. SG. 103/99, amend. SG. 53/00, amend. SG. 1/01, amend. SG. 102/01, amend. SG. 110/01, amend. SG. 75/02, amend. SG. 31/03) after the words "the education" shall be added "the medical establishments".

§ 32. In the Law of the foods (Prom. SG. 90/99, amend. SG. 102/03) everywhere the words "the state sanitary commission control" shall be substituted by "the state health control", the words "the Law of public health" shall be substituted by "the Law of health" and the words "chief state sanitary inspector" shall be substituted by "chief state health inspector".

§ 33. In art 24 of the Law of the foreigners in the Republic of Bulgaria (Prom. SG. 153/98, amend. SG. 70/99, amend. SG. 42/01, amend. SG. 112/01, amend. SG. 45/02, amend. SG. 54/02, amend. SG. 37/03, amend. SG. 103/03, amend. SG. 37/04) the words "health establishment" shall be substituted by "medical establishment".

§ 34. In art. 30. para 2 of the Law of tobacco and tobacco products (Prom. SG. 101/93, amend. SG. 19/94, amend. SG. 110/96, amend. SG. 153/98, amend. SG. 113/99, amend. SG. 33/00, amend. SG. 102/00, suppl. SG. 110/01, suppl. SG. 20/03, amend. SG. 57/04) the following amendments and supplements shall be made:

1. Item 1 shall be changed to:

"1. on the territory of creches and kindergartens, schools, hostels of students, medical and health establishments;"

2. item 5 shall be changed to:

"5. which do not correspond to the health requirements;"

3. In item 11 the words "in the sites, licensed for duty free trade" shall be deleted.

4. Item 16 shall be created:

"16. at sport events and public events, organised for children and students".

§ 35. In the Code for Social Insurance (Prom. SG. 110/99, amend. SG. 55/00, amend. SG. 64/00, amend. SG. 1/01, suppl. SG. 35/01, amend. SG. 41/01, amend. SG. 1/02, amend. SG. 10/02, amend. SG. 45/02, amend. SG. 74/02, amend. SG. 112/02, amend. SG. 119/02, amend. SG. 120/02, amend. SG. 8/03, suppl. SG. 42/03, amend. SG. 67/03, suppl. SG. 95/03, amend. SG. 112/03, amend. SG. 114/03, amend. SG. 12/04, amend. SG. 21/04, suppl. SG. 38/04, amend. SG. 52/04, amend. SG. 53/04, amend. SG. 69/04) art. 14, 15, 16 and 17 shall be repealed.

§ 36. In the Law of protection from discrimination (SG 86/03) the following supplements shall be made:

1. In art. 4, para 1 after the words "ethnic affiliation" shall be added "human genome".

2. In § 1 of the additional provisions item 14 shall be created:

"14. "Human genome" is combination of all genes in single (diploid) combination of chromosomes of given person."

§ 37. In the Law of the protection of the personal data (SG 1/02) the following supplements shall be made:

1. In art. 2, para 1 at the end shall be added "as well as the data of the human genome";

2. In § 1 of the additional provision item 10 shall be created:

"10. "Human genome" is the combination of all genes in a single (diploid) set of chromosomes of given person."

§ 38. In one year term after the law enters into force the Council of Ministers shall approve and the Minister of Health shall issue the normative acts for its implementation.

§ 39. Till the entering into force of the acts of § 38 the issued normative acts for the implementing of the revoked Law of public health shall be implemented as far as they do not contradict with this law.

§ 40. The fulfilment of the law shall be assigned to the Minister of Health.

§ 41. The law shall enter into force from January 1, 2005 except art. 53, para 3, which shall enter in to force from January 1, 2006.

The law is passed by the 39th National Assembly on July 29, 2004 and was affixed with the official seal of the National Assembly.

Transitional and concluding provisions (SG 85/05)

§ 17. (1) The higher schools shall ensure the training and the acquisition of educational – qualification degree "bachelor" in specialties of the professional direction

"health care" by the order of the Law of the higher education till the beginning of the educational year 2006/2007.

(2) The persons who have started their training in the specialties "nurse" and "midwife" of professional direction "Public health" of the educational – qualification degree "specialist" and till September 1, 2006 have not finished their education shall continue their training in faculty or branch of higher school during the following school year in the respective specialty of professional direction "Health care" for acquiring educational – qualification degree "bachelor" without competition examinations.

(3) The persons acquired educational – qualification degree "specialist" in the specialties of para 2 shall have the rights of the persons with educational – qualification degree "bachelor" after issuing of certificate for equaling by the Minister of Health. The certificate shall be issued upon existence of practice in the specialty acquired during the last 5 years under conditions and by order determined with ordinance of the Minister of Health.

(4) The persons who have started their training in the specialties "rehabilitator", "medical laboratory technician", "X-ray lab technician", "sanitary inspector" and "masseur" of professional direction "Public health", in the specialty "dental mechanic" of professional direction "Stomatology" and in the specialty "assistant pharmacist" of professional direction "Pharmacy" of the educational – qualification degree "specialist" shall continue their training in the same specialties for acquiring the same educational degree in professional direction "Health care".