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**221. RULEBOOK ON INTERNAL ORGANIZATION AND JOB
DESCRIPTIONS OF THE MINISTRY OF HEALTH**

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Pursuant to Article 37, paragraph 2 of the Law on Public Administration (Official Gazette of the Republic of Montenegro, No. 38/03, Official Gazette of the Republic of Montenegro, No. 22/08) upon proposal of the Ministry of Health, at its session held on _____, the Government of Montenegro, hereby issues the

**RULEBOOK
ON INTERNAL ORGANIZATION AND JOB DESCRIPTIONS OF THE MINISTRY OF HEALTH**

Article 1

This Rulebook shall lay down internal organization and job descriptions of the Ministry of Health (hereinafter referred to as the Ministry), and shall stipulate organizational units and their competence, work posts, trial work and employment of trainees.

I. ORGANIZATIONAL UNITS AND THEIR SCOPE OF WORK

The Secretary of the Ministry and the Advisor to the Minister shall perform their work outside the internal organizational units.

The organizational units are:

1. Health Care Sector

- 1.1 Department for Outpatient and Primary Health Care
- 1.2 Department for Inpatient Health Care
- 1.3 Department for Food Safety
- 1.4 Department for Health and Sanitary Inspection Activities

2. Sector for Health Care System Management

- 2.1 Department for Development
- 2.2 Department for Legislative Activities

Sector for Economics in the Health Care System

- 3.1 Department of Information Technology, Health Care Investments and Budget
- 3.2 Department for Health Insurance and Contracting

3. Sector for Quality Promotion and Control

- 4.1 Department for Institutional Accreditation
- 4.2 Department for Patients' Rights

4. Sector for Bioethics and Pharmaceutics

- 5.1 Department for Pharmaceutics
- 5.2 Department for Bioethics, Genetics and Transplant Programmes

5. Division for European Integration and International Cooperation

6. Drugs Division

7. Office of the Minister

8. Department for General Affairs and Finance

9. Regional Units of Health and Sanitary Inspection

10.1 Regional Unit Podgorica, for municipalities Podgorica, Danilovgrad, and Cetinje

10.2 Regional Unit Nikšić, for municipalities of Nikšić, Šavnik, and Plužine

10.3 Regional Unit Bijelo Polje, for municipalities of Bijelo Polje, Mojkovac, and Kolašin

10.4 Regional Unit Berane, for municipalities of Berane, Plav, Rožaje, and Andrijevica

10.5 Regional Unit Pljevlja, for municipalities of Pljevlja, and Žabljak

10.6 Regional Unit Bar, for municipalities of Bar and Ulcinj

10.7 Regional Unit Herceg Novi, for municipalities of Herceg Novi and Kotor

10.8 Regional Unit Budva, for municipalities of Budva and Tivat

Article 2

- 1. Health Care Sector** shall perform activities related to implementation of the health care policy which lays down general principles of the system and organization in the area of primary, secondary and tertiary health care based on the principle of equality in exercising right to health care. It shall monitor reports on health status of the population prepared and submitted by the Institute of Public Health, organize measures for implementation of health care; it shall monitor the exercise of right to health care, supervise the work of health institutions and supervise the enforcement of the law and regulations for implementation of health care measures. It shall grant its approval to prevention programmes; elaboration of studies and programmes related to work organization and development of health care service; it shall coordinate and monitor the work of the Chamber of Physicians and Chamber of Pharmacists, supervise and inspect the legality of work of chambers and, upon their proposal, lay down the contents and manner of issuing practice permits; it shall conduct measures of inspection control in pursuance of the law, inspect enforcement of the law and other regulations regarding citizens' health care from the Ministry's capacity, reach decisions in second-instance administrative procedure on the rights to health insurance and sanitary inspection.

1.1 Department for Outpatient and Primary Health Care shall perform activities related to preservation and promotion of citizens' health, monitoring health care needs of the population, and organization of institutions on the primary health care level, professional elaboration of systemic and other issues related to monitoring and examination of conditions in primary health care; professional elaboration of issues related to monitoring and examination of conditions in private practice in terms of human resources, scope and content of work, outfitting and keeping up-to-date with medical technology.

1.2 Department for Inpatient Health Care shall perform activities related to system monitoring, organization and development of secondary and tertiary health care; it shall monitor development of secondary and tertiary health care; it shall keep up-to-date with the studies and experiences of developed countries in the field of health care, development and planning of inpatient health care and application of modern technologies. It shall organize supervision of professional activities of secondary and tertiary health care, professional elaboration of systemic and other issues related to monitoring and examination of conditions in the health care service in terms of type and catchments areas of health institutions, private practice, human resources, scope and content of work and outfitting; it shall prepare plans and implement measures for rationalization in terms of system monitoring; it shall analyze the effects of inpatient health care through operation,

organization and development, it shall monitor the application of regulations and standards of health care of the population; it shall propose measures for promoting health care quality.

1.3 Department for Food Safety shall perform activities related to elaboration of regulations in this area; adoption of the annual control plan, monitoring plan, plan for crisis management in the area of vegetable food safety after primary production, combined food and other types of food; cooperation with international organizations and competent bodies of other countries; determining the fulfilment of prescribed requirements; issuance of permits or approvals for performing activities to entities dealing with the food of vegetable origin after primary production, combined food and other types of food; keeping records of facilities for production and trade in foodstuffs; elimination of facilities from the registry of approved facilities; drawing up reports in the area of food safety.

1.4 Department for Health and Sanitary Inspection Activities shall perform activities of inspection control over enforcement of the law and other regulations related to the fulfilment of requirements for performing the work of health institutions, the quality of work, organization of work, organizational-legal and status changes of health institutions, manner of keeping and using prescribed medical records. It shall perform supervision over enforcement of the law and other regulations related to prevention and control of communicable diseases, potable water, objects and devices for potable water supply, supervision of food safety in all facilities used for production and trade in foods of vegetable origin after primary processing, combined and other types of food, retailed animal feeds, which have an individual declaration and packaging and general-purpose objects which are subject to health and sanitary inspection, medical waste and other objects which are subject to sanitary inspection. It shall inspect the enforcement of the law and other regulations on the area of sanitary and hygienic and anti-epidemic protection of people, preventive sanitary inspection of public utilities, supervision of persons employed in these facilities, supervision of production and trade in medicines and poisonous substances, issuance of sanitary permits for locations, construction and reconstruction projects, and permits for putting into operation industrial polluter plants, water supply and sewerage facilities, health and social institution facilities, catering facilities, tourist settlements and transportation means, facilities for disposal of waste water and other substances from built-up areas, industrial plants, health care facilities and residential buildings. It shall prepare information and reports and propose specific measures from its scope of work. It shall perform administrative activities related to inspection control, undertake measures for initiating proceeding before competent bodies against perpetrators of criminal offences, corporate offences and infractions.

Article 3

- 2. Sector for Health Care System Management** shall perform activities related to creating health policy, development and promotion of the health care system through components of health infrastructure – resources, management and organization. It shall prepare studies, analyses, studies, information and programmes which shall serve as a professional basis for development and implementation of policy in the area of health care and health insurance. It shall give its opinion on proposals for laws and other regulations, it shall provide its interpretation of regulations in the field of health insurance, perform supervision over legality of work of the Health Insurance Fund. It shall prepare planned documents from its capacity: residency plans, advanced training programmes, development priorities, health institutions network. It shall propose criteria for establishment and operation of health institutions, content and scope of health care (with standards), monitor implementation of resolutions, declarations and conventions in the area of health care. It shall prepare proposals of action plans and programmes intended for protection of vulnerable groups and reduction of inequality in health care. It shall prepare and monitor implementation of the national strategy of public health. It shall coordinate and monitor the work of permanent expert bodies – ministry commissions in charge of developing strategies in priority areas of health care and other appropriate activities; it shall prepare draft laws and other regulations

in the area of health care and health insurance, regulate in more detail the manner of providing health care and fulfilment of requirements for establishment and work of health institutions. It shall define professional medical activities related to provision of health care, professional development of health workers and associates, and conditions for performing training programmes and taking professional exams. It shall draw up proposals of programmes and duration of residencies. It shall prepare proposals and coordinate activities of liaison bodies regarding implementation of international agreements on health insurance.

2.1 Department for Development shall perform activities related to creation of health policy, development and promotion of the health care system through health infrastructure components – resources, management and organization. It shall prepare studies, analyses, studies, information and programmes which serve as a professional basis for development and implementation of policy in the area of health care and health insurance. It shall give its opinion on proposals for laws and other regulations; it shall provide its interpretation of regulations in the field of health insurance. It shall prepare planned documents from its capacity: residency plans, advanced training programmes, development priorities, health institutions network. It shall propose criteria for establishment and operation of health institutions, content and scope of health care (with standards), monitor implementation of resolutions, declarations and conventions in the area of health care. It shall prepare proposals of action plans and programmes intended for protection of vulnerable groups and reduction of inequality in health care. It shall prepare and monitor implementation of the national strategy of public health. It shall coordinate and monitor the work of permanent expert bodies – ministry commissions in charge of developing strategies in priority areas of health care.

3. **2.2 Department for Legislative Activities** shall perform activities related to preparation of draft laws and other regulations in the area of health care and health insurance; it shall regulate in more detail the manner of providing health care and fulfilment of requirements for establishment and work of health institutions. It shall define professional development of health workers and associates, and conditions for performing training programmes and taking professional exams. It shall draw up proposals of programmes and duration of residencies. It shall prepare proposals and coordinate activities of liaison bodies regarding implementation of international agreements on health insurance.

Article 4

4. **Sector for Economics in the Health Care System** shall perform activities related to monitoring of the financing and contracting system between public health institutions and the Health Insurance Fund; it shall give its opinion of the Financial Plan of the Fund, give its approval to annual needs balance, submit proposed prices of health care services, monitor the privatization programme in health care; give its opinion of Fund's proposals about concluding contracts on providing health care, participation of insured persons in health care costs; prepare projections of financial assets for health care, estimate budgetary resources for funding specific forms of health care, prepare and monitor implementation of economic policy measures in the health care system; monitor public procurement in public health institutions, adopt capital investment plan and overall expenditure in the health care system in order to attain financial sustainability of the health care system, which relates to promotion and operation of the health care system, preparation, monitoring and implementation of strategy for development of information society; prepare proposals of action plans and programmes for promotion and development of operating the health care information system, define activities for setting up technological and secure information infrastructure in health care bodies and institutions. It shall supervise implementation of electronic files of patients in primary, secondary and tertiary health care.

3. 1 Department for Information Technology, Health Care Investments and Budget shall perform activities related to development of capital investment plan in the health care

system, monitor public procurement in public health institutions; prepare projections of financial assets; prepare projections of financial assets for health care, estimate budgetary resources for funding specific forms of health care; prepare proposals of action plans and programmes for promotion and development of operating the health care information system, define activities of setting up technological and secure information infrastructure in health care bodies and institutions. It shall supervise implementation of electronic files of patients in primary, secondary and tertiary health care.

3. 2 Department for Health Insurance and Contracting shall perform activities related to monitoring the financing and contracting system between public health institutions and the Health Insurance Fund; it shall give its opinion of the Financial Plan of the Fund, give its approval to annual needs balance, submit proposed prices of health care services, monitor the privatization programme in health care; give its opinion of Fund's proposals about concluding contracts on providing health care, participation of insured persons in health care costs; prepare and monitor implementation of economic policy measures in the health care system; overall expenditure in the health care system in order to attain financial sustainability of the health care system, which relates to promotion and operation of the health care system.

Article 5

4. Sector for Quality Promotion and Control shall perform activities related to promotion of the system of voluntary accreditation of institutions; promotion of accreditation standards at all levels of health care; development and publication of reports on accreditations of health institutions; formulating procedures of admittance to treatment and discharge of patients; monitoring, upgrading, and promotion of quality indicators and work results in health institutions; revision of criteria for placing patients on waiting lists; revision of existing and establishment of new procedures for placing patients on waiting lists; development of guidebooks and procedures for respecting patients' rights; analyses of results on the satisfaction of beneficiaries with provided health services; establishment of clinical protocols and guidelines.

4.1 Department for Institutional Accreditation shall perform activities related to promotion of the system of voluntary accreditation of institutions; promotion of accreditation standards at all levels of health care; development and publication of reports on accreditations of health institutions; monitoring, upgrading, and promotion of quality indicators quality and work results in health institutions; development of guidebooks and procedures for respecting patients' rights; analyses results on the satisfaction of beneficiaries with provided health services; establishment of clinical protocols and guidelines.

4.2 Department for Patients' Rights shall perform activities related to revision of criteria for placing patients on waiting lists; revision of existing and establishment of new procedures for placing patients on waiting lists; development of guidebooks and procedures for respecting patients' rights; analyses of results on the satisfaction of beneficiaries with provided health services; formulating procedures of admittance to treatment and discharge of patients;

Article 6

5. Sector for Bioethics and Pharmaceuticals shall perform activities from the scope of work of the Ministry related to drafting proposals and analyses for implementation of the national policy in the area of pharmaceuticals and medical devices; participation in preparation and implementation of international agreements and implementation of international cooperation in the area of pharmaceuticals and medical devices; drafting studies of analyses and studies in the area of pharmaceuticals and medical devices; establishment of the national pharmacopeia and magistral formula; establishment of measures for rational consumption

of medicines; prescribing more detailed conditions for issuance of permits for medicine marketing, production, control, monitoring of undesired reactions, advertising and marking traditional homeopathic medicines; prescribing the content and the manner of keeping records of issued permits; issuance of permits for import, export and marketing of poisonous substances; keeping the Registry and the List of Poisonous Substances; monitoring of trade and use of poisonous substances; compiling waiting lists for persons who must resort to transplantation of a body part as the only way of treatment, keeping the registry and records of potential body part donors, adoption of documents for application of the Law on Retrieval and Transplantation of Human Body Parts and the Law on Assisted Reproductive Technologies, keeping a single registry of procedures of assisted reproductive technologies and the registry of collected, selected and stored reproductive cells, application of scientific achievements in biomedicine in health care and treatment; application of gene technology for treatment of medically indicated cases; conducting activities in drafting secondary legislation for implementation of the

6. Genetic Privacy; issuing accreditation for genetic testing laboratories in line with EU standards and prosecution of second instance administrative proceedings in the area of pharmaceuticals and medical devices.

5. 1 Department for Pharmaceuticals shall perform activities related to drafting proposals and analyses for implementation of the national policy in the area of pharmaceuticals and medical devices; it shall participate in preparation and implementation of international agreements and implementation of international cooperation in the area of pharmaceuticals and medical devices; drafting studies of analyses and studies in the area of pharmaceuticals and medical devices; establishment of the national pharmacopeia and magistral formula; establishment of measures for rational consumption of medicines; prescribing more detailed conditions for issuance of permits for medicine marketing, production, control, monitoring undesired reactions, advertising and marking of traditional homeopathic medicines; prescribing the content and the manner of keeping records of issued permits; issuance of permits for import, export and marketing of the medicine; keeping the Registry and the List of Poisonous Substances; monitoring of trade and use of poisonous substances and prosecution of second instance administrative proceedings in the area of pharmaceuticals and medical devices.

5. 2 Department for Bioethics, Genetics and Transplant Programmes shall perform activities related to compiling waiting lists for persons who must resort to transplantation of a body part as the only way of treatment, keeping the registry and records of potential body part donors, adoption of documents for application of the Law on Retrieval and Transplantation of Human Body Parts and the Law on Assisted Reproductive Technologies, keeping a unique registry of procedures of assisted reproductive technologies and the registry of collected, selected and stored reproductive cells, application of scientific achievements in biomedicine in health care and treatment; application of gene technology for treatment in medically indicated cases; conducting activities in drafting secondary legislation for implementation of the Law on Genetic Privacy; issuing accreditation for genetic testing laboratories in line with EU standards.

Article 7

6. **Division for European Integration and International Cooperation** shall perform activities from the scope of work of the Ministry related to monitoring the performance of activities and obligations of the Ministry in the process of association and accession to the EU in the area of the health care system; it shall provide information on implementation of the Action Plan for the area of the Ministry, define donation programmes, cooperation with competent authorities and institutions regarding the process of EU accession and monitor activities of these authorities in the process of EU accession; it shall prepare programmes, information and reports from this area; it shall monitor implementation of international resolutions, declarations and conventions in the area of health care, provide submission of national

reports on health upon request of the World Health Organization and other indicators for assessment of the health status in line with international conventions.

Article 8

7. **Drugs Division** shall monitor implementation of aims stipulated by the National strategic response to drugs and the Action Plan; it shall monitor and perform national coordination of multi-sectoral implementation of policy in the area of drugs, so as to provide a comprehensive response to issues from the national level; it shall set up and maintain a national horizontal and vertical contact network; it shall monitor implementation of activities between state bodies, institutions, the local government, the civil sector and drafting of the National programme proposal; it shall participate in drafting legislative acts and other documents and update them so that they comply with international and EU documents and standards. It shall monitor the application of measures from the domain of the health care system, social care, preventive, therapeutic, rehabilitative activities from all line ministries, and activities from the domain of customs and police services, the NGO sector; it shall establish and maintain international cooperation with relevant international bodies, UNODC, EMCDDA, WHO, POMPIDOU group; it shall coordinate drafting of mandatory annual report for EMCDDA and data for REITOX; it shall submit regular and special reports to international organizations and associations; it shall establish and maintain regional and neighbourly cooperation in line with the European drugs strategy; it shall cooperate with international institutions in order to promote therapeutic and rehabilitative activities related to addiction to psychoactive substances; it shall set up and keep a database in the area of drugs in the country; it shall coordinate drafting of the National report; propose members of the Expert Drugs Council which shall be appointed by the Government of Montenegro and assure the implementation of decisions adopted by the Expert Council of the Government; it shall propose measures and activities related to drugs to the Expert Council, and perform administrative activities for the Expert Council.

Article 9

8. **Office of the Minister** shall perform professional, organizational and administrative-technical activities necessary for performing the office of the minister; activities of preparation and execution of internal and external communication; activities related to public relations; communication with the Government of Montenegro and other state administration bodies; organization of meetings and public appearances, creating websites of the Ministry.

Article 10

9. **Department for General Affairs and Finance** shall perform activities related to monitoring laws and other regulations regarding civil servants and employees; it shall prepare general documents of the Ministry and individual documents which stipulate the rights, obligations and responsibilities of employees of the Ministry; it shall execute procedures related to: employment, evaluation, promotion, acknowledgement of capacity, professional development, training of employees, qualifying trainees for independent execution of work; it shall keep single records of human resources and other records in the area of work; it shall prepare statements before the Administrative Court against complaints of civil servants and employees and comply with the rulings passed in administrative dispute; it shall draw up and implement the Budget of the Ministry; it shall draw up the financial plan; it shall use assets promptly and appropriately for purposes stipulated by the Budget and the financial plan; it shall keep business books, interim statements and annual balance sheets, draw up financial statements and submit data to the Treasury; it shall prepare accounting lists for calculating wages and other income of the Ministry; cash operations and other financial and accounting operations; it shall admit, distribute, keep records and put

documents into operation and dispatch them; archive cases; photocopy and reproduce; requisition office material; personally submit summons to hearing and rulings passed in first instance misdemeanour procedure; it shall include posts of drivers and other ancillary affairs.

Article 11

10. Regional Units of Health and Sanitary Inspection shall perform regular activities of health and sanitary inspection supervision and control over enforcement of the law and other regulations in the area of sanitary and hygienic protection, epidemiologic supervision in cooperation with the Institute and health institutions, preventive inspection control of facilities under special supervision: health and educational institutions, public transportation means and potential pollutants, industrial plants, facilities for production and trade in foodstuffs and general-purpose objects, facilities and devices for potable water supply, supervision over food safety in all facilities where food of vegetable origin is produced and traded after primary processing, supervision of combined and other types of food and animal feed retailed with an individual declaration and packaging, and general-purpose objects subject to health and sanitary inspection and other facilities which are subject to sanitary inspection, catering facilities, residential buildings, facilities for waste water disposal and inspection of trade in goods, and the movement of people at border crossings and their respective catchment areas.