



Number: 5-040/25

Podgorica, January 9, 2025

MINISTRY OF HEALTH

(name of the ministry that conducted the public hearing)

REPORT ON THE CONDUCTED PUBLIC HEARING

Draft law on health care

(name of the draft law that was the subject of public discussion)

The duration of the public hearing: 20 days. The Ministry of Health announced a public debate on the Draft Law on Health Care from 11.11. 2024 until December 2, 2024.

The manner of conducting the public hearing: The Ministry of Health issued a public invitation to citizens, the professional public and all other interested parties to join the public discussion and contribute to the consideration of the Draft Law on Health Care by submitting comments, proposals and suggestions in written and/or electronic form, to the e-mail addresses: milica.golubovic@mzd.gov.me i kabinet@mzd.gov.me, as well as by holding a round table in Podgorica at the Institute for Public Health of Montenegro, on November 26, 2024.

Authorized representatives of the ministry who participated in the public debate: Mr Mirjana Vlahović Andrijašević, State Secretary; Dr. Ognjen Delić, Acting Director of the Directorate for Health care, Regulated Professions and Supervision of the Functioning of Professional Regulatory Bodies; Milica Golubović, head of the Directorate for monitoring international standards and national regulations in the field of health care; Slavojka Šuković, Head of the Directorate for Normative Affairs; Ljiljana Vujisić, Head of the Directorate for Health Care

Data on the number and structure of participants in the public debate: During the public debate on the Draft Law on Health Care, the interest of a significant number of health workers and health associates, representatives of health institutions founded by the state, associations of private practice doctors, representatives of health institutions owned by the private sector, professional associations of health workers, natural persons and a significant number of proposals and suggestions was expressed.

At the round table held on November 26, 2024 at the Institute of Public Health of Montenegro, in addition to the representatives of the proponents, there were



representatives of: The Chamber of Doctors, the Chamber of Pharmacy, the Union of Health Workers, Dental Workers of Montenegro, the Chamber of Physiotherapists, Private healthcare institutions, and a certain number of health workers and health associates.

Summary of submitted comments, proposals and suggestions, with stated reasons for their acceptance or non-acceptance:

1. UNICEF Representation for Montenegro/Ida Ferdinandi, in the submitted suggestions, she proposed: to amend Article 19, in such a way as to add a new paragraph which reads "timely detection of delays or deviations in the typical development of the child as well as disturbances and difficulties in the child's development and timely early intervention".

The proposal is accepted

- in Article 20 point 2, make a technical correction.

The proposal is accepted

- in Article 29, point 33, instead of "early intervention", expand the wording to: "monitoring of child development, counseling in the field of early development and early intervention".

The proposal is accepted

- in article 42, paragraph 3, to delete the option of an outpatient maternity hospital.

The proposal is not accepted

Explanation

We appreciate all the suggestions given in the explanation, but due to the specificity of certain areas of Montenegro, the proposal is not accepted.

In the coming period, the Ministry of Health will make additional efforts to eliminate the shortcomings that have been pointed out, especially in terms of missing space, equipment and staff training.

- in Article 85, paragraph 1, replace the words: "improvement of mental health" with the words: "improvement of health, development and well-being of the child".

- in point 1 of this article, replace the words: "performs diagnostics" with the words: "implements professional and scientific foundation of diagnostic methods and proposes effective, timely, scientifically based early intervention measures and ways of their continuous implementation".

- in point 3, replace the words: "coordinates the work of support centers at health centers, day and resource centers" with the words: "coordinates the work of support centers at health centers, day and resource centers and preschool institutions".

The proposal is accepted

In Article 110, add the words that health associates perform the health activity of "early intervention for children with developmental delays and disabilities".

The proposal is accepted

In Article 111, paragraph 2, add the words: "early intervention for children with developmental delays and disabilities" among the exceptions for the provision of services outside a health care institution, and in Article 41, paragraph 2, except for physical therapy, add the words: "and early intervention services".

The proposal is accepted



In Article 135, paragraph 1 should be amended to read: "Continuous medical education includes continuous monitoring of the development of medical and other sciences, acquisition of new knowledge and skills in order to maintain and improve the quality of healthcare..." and supplement by adding point 3) participation in professional supervision of healthcare workers and associates in order to improve professional work.

The proposal is not accepted

Continuous medical education includes monitoring the development of medical science. In Article 144, add chambers of nurses/technicians and midwives.

The proposal is not accepted

The establishment of the Chamber of Nurses/Technicians and Midwives is prescribed by the Law on Health Care.

In Article 170, add as a separate point (competency) "conducting skin-to-skin contact after the birth of the child and providing support to the mother in breastfeeding, including early initiation of breastfeeding (early initiation of breastfeeding).

The proposal is accepted

In Article 215, the words: "advises the mother that the newborn should use an adapted milk formula that meets its nutritional needs" should be replaced with the words "gives the mother or parent written instructions and individual training on the risks of use, safe methods of preparing and applying milk formula. And that the content of the written instructions is prescribed by the Ministry.

The proposal is not accepted

The submitted proposal is for protocols and not for a legal norm.

In Article 217, he proposes to include other important aspects of early child development, adding the wording: "as well as advice on stimulating the development of the newborn, safety of the newborn, mental development of the mother".

The proposal is not accepted

The proposal is a matter for expert recommendations and not for a legal norm.

Article 219 should be amended in terms of expanding the scope of the ban on advertising adapted milk formulas.

The proposal is not accepted

The prohibition of advertising is regulated by another regulation.

Art. 256 and 257 amendments with the introduction of a penal provision for advertising adapted milk formula for newborns and infants".

The proposal is not accepted

As previously stated, bans on the advertising of baby food have been sanctioned and this would be an over-regulation of the provision.

2. Dr. Iva Ivanović, specialist in child and adolescent psychiatry, submitted suggestions to amend Article 85 in such a way as to expand the competences of the Center for Early Development

The proposal is accepted

The suggestions are identical to the suggestions submitted by the Unicef representative office for Montenegro, which were accepted as stated above.



3. Private healthcare institution Polyclinic Dr. Vuksanović, submitted suggestions that in Article 49, paragraph 1, the words: "for which it establishes clinics" should be deleted

The proposal is not accepted

A polyclinic, as a type of health institution, organizes its work through clinics that are an integral part of that health institution.

Article 88 paragraph 1 shall be amended in such a way that after the words: "Health institution" the words: "whose founder is the state or municipality" will be added.

The proposal is accepted

In Article 113, make a correction in such a way that the words: "67 years of life" are replaced by the words: "66 years of life".

The proposal is accepted

Technical error.

In Article 139, paragraph 1, make a correction and clarify the reference to Article 138.

The proposal is accepted

In Article 262, correct the technical error and specify the reference to the corresponding article.

The proposal is accepted

4. Union of Freelancers of the Clinical Center of Montenegro, submitted a proposal to include in the Law on Health Care a provision that medical workers employed in the Clinical Center of Montenegro should receive a salary increase of at least 10% compared to other employees in the health care system, with the explanation that secondary and tertiary level health care services are provided in the Clinical Center of Montenegro. Furthermore, they state that in the Clinical Center of Montenegro, almost 70% of all health services in the country are performed, which are not valued through the earnings of the employees. The complexity, volume of work, increased possibility of professional error and the body of service provision must be additionally evaluated and additionally paid through legally increased earnings, which would be an unchangeable category regardless of Branch collective agreement and its changes.

The proposal is not accepted

Explanation

Regulating the wages of employees in the health care system is not subject to the Law on Health Care, but to the Law on Wages in the Public Sector.

5. Primarijus Safet Lješnjani, MD, PhD, specialist in gynecology and obstetrics from Plav, suggests a proposal that in all health institutions, not only in the Clinical Center of Montenegro, Institute of Public Health, Monefarm, the Institute for Emergency Medical Assistance, Clinical Hospital Centers, the Institute for Blood Transfusion and the Health Center of the capital, the Board of Directors is established as the governing body of the health institution. In this way, certain irregularities that are present in health institutions that do not have a Board of Directors as a management body, but these tasks are performed by the director of the health institution, would be suppressed.

The proposal is not accepted

Supervision of the work of health institutions that do not have a Board of Directors is carried out through quality control, which is carried out by the Commission of the Ministry



as well as the competent inspection. Reasons of economy and rationality preclude the need to organize a Board of Directors in all health institutions.

6. Dr. Savo Radunović, doctor of chiropractic, proposes that in Article 198, paragraph 3, the composition of the Commission for evaluation and giving opinions on the application of methods and procedures of complementary medicine be supplemented, in such a way that a representative from the field of complementary medicine is also a member of the commission.

The proposal is accepted

7. Private healthcare institution Polyclinic "MOJ LAB", Podgorica, in the submitted suggestions, points out that as part of the definition of a day hospital, only interventions that require local anesthesia are allowed, which is not correct, if it is taken into account that certain interventions that can be performed in a day hospital with analgosedation and the patient stays in the institution for less than 24 hours.

The proposal is accepted, and interventions in the day hospital with the application of analgosedation are allowed in situations where the provided health service requires patients to stay in the day hospital for less than 24 hours.

In Article 58, paragraph 2, delete the words: "as well as health institutions that provide interventional cardiology procedures", because this provision is discriminatory and unjustifiably prevents the private sector, which can provide the necessary personnel, spatial and technological capacities to provide this health service to patients.

The proposal is accepted

In Article 61, paragraph 2, item 10, the words: "other relevant evidence" should be deleted in order to avoid the possibility of requesting different certificates and evidence from case to case.

The proposal is accepted

In Article 88, paragraph 4, it is prescribed that for the leasing of space and equipment and other means, it is necessary to obtain the consent of the Ministry. It is necessary to specify that this refers to health institutions founded by the state or municipality.

The proposal is accepted

In Article 204, it is necessary to specify the method of keeping medical records.

The proposal is accepted

It is prescribed that medical documentation be kept in electronic form and it is specified in which situation an exception is prescribed.

8. Ministry of Justice, i.e. the Directorate for Execution of Criminal Sanctions and Control, in its letter indicates that it is necessary to equate health workers employed in this body with the status of health workers in the public sector and that it is necessary to provide persons deprived of their liberty and persons serving prison sentences with the same health services as other patients in the health system. In addition, they state that it is necessary for the prison hospital to be part of the public health system.

The proposal is partially accepted

Explanation

The status of health workers who are employed in the Administration for the Execution of Criminal Sanctions in which they provide health care is not the subject of this law. Wages



are regulated by the Law on Wages in the Public Sector. Education and professional development is not in question. When it comes to the health care of persons who are detained or serving a prison sentence, they are recognized by the current law on health care and have appropriate health care, in accordance with the law.

The proposal is accepted that the Authority for the Execution of Criminal Sanctions can also organize a health facility for the execution of security measures, mandatory psychiatric treatment and care in a health facility, mandatory treatment of alcoholics and mandatory treatment of drug addicts, as well as for the treatment of acute psychiatric conditions of persons deprived of liberty, and that this health facility be organized as a special hospital, in accordance with this law.

9. Dental Chamber of Montenegro, submitted the following proposals: to amend Article 165 in such a way as to prescribe that the Chamber issues a license to a dentist who meets the conditions for issuing a license, which proves the professional competence for independent performance of all dental activities, except for activities in the field of jaw orthopedics and maxillofacial surgery.

The proposal is not accepted

Explanation

A healthcare worker receives a license after passing a professional exam for general dentistry. After completion of specialization in the appropriate field, the competent chamber issues a license for that specialist branch.

To add a new item to Article 146, paragraph 1, which would prescribe that the Dental Chamber determines the minimum prices for health services in private dental institutions, with the consent of the Ministry.

The proposal is not accepted

Explanation

Determining the prices of dental health services that are not covered by mandatory health insurance in the proposed way is unsustainable. The prices of services in the health sector for institutions established by the state are determined by the Health Insurance Fund with the consent of the Ministry. Formation of prices for dental health services by the Dental Chamber for the private sector is not acceptable. Prices are dictated by the market and free competition. Otherwise, anything else would create a business barrier.

To amend Article 146 in such a way that the Ministry requests the opinion of the competent chamber on all issues related to the health care system.

The proposal is not accepted

Explanation

The creator of the health policy is the Ministry of Health and the working bodies are always represented by representatives of the competent chambers. In direct communication, appropriate solutions are found for the benefit of healthcare workers and public health.

That Article 140 paragraph 1 be amended in such a way as to stipulate that foreigners (except from Croatia, Serbia, Bosnia and Herzegovina, Slovenia and Macedonia) receive a dental license after passing a professional exam in the Montenegrin language, before the committee of the Dental Chamber. He states that the significant influx of foreigners who, in terms of issuing a license, are equal to doctors of dentistry who are citizens of Montenegro, results in the unequal position of dentists during employment in their own



country, which is unsustainable. The current regulations stipulate that a foreigner can start working in Montenegro only when he receives a residence permit from the competent Ministry, and when he has an invitation letter from a certain health institution to work there. The license is issued for a limited period and is tied to the duration of the residence permit. He states that foreigners do not know the Montenegrin language well enough, and that the verification of their professional qualifications is not carried out is unacceptable.

The proposal is not accepted

Explanation

Acceptance of this proposal would create discrimination. Foreigners receive a license in accordance with the law. They take the professional exam before the commission of the Ministry in the Montenegrin language. The validity of their diplomas is valued by the competent authorities, and therefore states that their expertise is not valued cannot be accepted.

That article 195 paragraph 4 decisively prescribes which authority, that is, which health institution is competent to issue a certificate to a doctor of dentistry.

The proposal is not accepted

Explanation

It is already prescribed in the mentioned article that it is a certificate issued by a health institution or other body accredited for the implementation of education for the performance of these methods.

That article 31 stipulates that an outpatient clinic is opened for emergency dental conditions at every emergency medical service in Montenegro.

The proposal is not accepted

Explanation

The Health Insurance Fund has concluded contracts with dental healthcare institutions for the provision of services in emergency situations.

Also, in the submitted suggestions, the Dental Chamber proposes to regulate the introduction of nitrous oxide (N₂O) sedation without the presence of an anesthesiologist in everyday dental practice.

The proposal is not accepted

Explanation

There is no need to separately regulate the introduction of nitrous oxide sedation for dental services, if it is also used in other procedures of providing health services in accordance with the law.

That in Article 139, paragraph 8, the words: "the amount of the costs of issuing and renewing the license" should be deleted

The proposal is accepted

To add a new paragraph in Article 122 that reads: "Medical and dental nurses also have the right to perform an internship, in accordance with the training program, under the supervision of a health worker with appropriate qualifications in health institutions that meet the conditions for performing an internship."

The proposal is not accepted

Explanation



Article 122 paragraph 1 already prescribes the right of healthcare workers and healthcare associates to carry out an internship and the obligation of healthcare institutions (meaning institutions founded by the state or municipality. This does not mean that healthcare institutions in the private sector cannot enable this) to provide them with this right, while this right applies to all healthcare workers and healthcare associates regardless of the level of qualification. Training is carried out in accordance with the program prescribed in paragraph 2 of the mentioned article. More detailed conditions for performing an internship will be regulated by a rulebook.

10. Dr Anđelka Duborija, president of the Professional Union of Dental Service Employees (SSZSS) in the submitted suggestions, in relation to the provision of Article 12 point 2, the duty of citizens to respect the scheduled examination and screening, it is proposed to prescribe compensation for damages or a penalty caused by missing the scheduled appointment and screening.

The proposal is accepted

Explanation

Also, in the submitted suggestions, it is pointed out that Article 29 of the services provided at the primary level of health care should be amended in such a way that, in point 20 also adds prevention services

The proposal is accepted

It also suggests that Article 30 be supplemented with orthodontic services.

The proposal is not accepted

Explanation

Orthodontic services are specialist services and are provided at the secondary level of health care. The package of services that insured persons receive at the primary level of health care is prescribed by a secondary legal act based on the Law on Compulsory Health Insurance.

In addition to the above, it points out that it is unclear in Article 93 in what sense the orthodontic appliance is mentioned in the hospitality establishment and that this should be clarified.

The proposal is accepted

- in Article 104, disputed is the provision that the Ministry prescribes the way of organizing and determining working hours in private practice with the rationale that private individuals must have privacy and freedom of personal organization and that this norm should be deleted.

The proposal is not accepted

Explanation

All entities in the health/dental service delivery system must adhere to prescribed working hours. In addition, when submitting a request for a decision on the fulfillment of the conditions for performing health care activities, the applicant states, among other things, whether the services will be provided in one or two shifts, whether the work will be performed twice or once. Therefore, there is no basis for contesting the provisions of Article 104.

That the provisions of Article 107, which regulates the additional work of health workers and health associates, are contradictory and that they should be corrected.



The proposal is accepted

IN Article 122 specifies that the obligation refers to health institutions founded by the state or municipality.

The proposal is accepted

In Article 138, which governs the obligation to have a license, it is disputed that dentists provide dental health services in the scope for which they have received a license, because in practice it is difficult to make a clear demarcation for certain dental services provided by a dentist and a dentist with a certain specialization, i.e. it is difficult to delineate what is general and what is specialist.

The proposal is not accepted

Explanation

A health worker provides health services in the scope for which he holds a license. Overlapping of duties in practice can be questionable when in a certain case the issue of responsibility for the quality of the health service provided arises, and therefore everyone is obliged to provide health services in the scope for which he received a license from the competent chamber.

That in Article 139, the words "that the costs of issuing a license shall be carried by the applicant for a license" be deleted, emphasizing that issuing a license is a job performed by the Chamber, as a transferred job of the Ministry of Health, for which the Chamber receives certain funds from the budget.

The proposal is accepted

That mandatory membership in the chamber for health workers working in the profession be deleted from Article 144, while emphasizing, among other things, that this norm is unconstitutional.

The proposal is not accepted

Explanation

Bearing in mind the fact that health workers exercise their rights (obtaining a license, education, evaluation, license renewal, etc.) through the Chamber, he states that the membership of health workers who directly provide health services is not mandatory, which is debatable. Chambers of health workers as a professional association is present in all surrounding countries.

That Article 193 is unclear. It is not known who issues the license for the use of new health technology and why it is needed to carry out procedures from the aesthetically minimally invasive non-surgical method of treatment. He also states that these procedures have been in use for decades and cannot be called new. He proposes to simplify procedures due to the necessity of legalizing work in the field of facial aesthetics, for which doctors have qualifications.

The proposal is not accepted

Explanation

The provision of Article 193 precisely defines that the Ministry issues a permit for the use of new health technology based on the opinion of the Commission composed of prominent health workers. Aesthetically minimally invasive methods can be applied only under prescribed conditions.

- Article 200 should be amended in such a way that orthodontists are added to the system of referring patients from the primary to the secondary and tertiary levels.



The proposal is accepted

11. American Chamber of Commerce/AmCham, in the submitted suggestions, it indicates that the provision in Article 58, among other things, which stipulates that only the state can establish a health facility where "interventional cardiology procedures" are performed, is discriminatory and should be deleted.

The proposal is accepted

12. Center for Forensic Medicine The Clinicač Center of Montenegro/Director of the Center for Forensic Medicine Dr. Ivana Čurović Šoškić, specialist in forensic medicine, submitted a suggestion to amend Article 243 in such a way as to delete the deadline for autopsy work (24 hours after the person's death). It often happens that the autopsy is done later, when more than one autopsy is done in one day/days, and within 24 hours after death, it should be deleted.

The proposal is accepted

Also, the Center for Forensic Medicine points out that it is necessary, in the spirit of distinguishing between the term pathological anatomy and forensic autopsy, to clarify that the autopsies from paragraph 1 point 4 and 7 to 9 are performed by one or more pathology specialists, and the autopsies from point 5 and 6 by one or more forensic medicine specialists. Natural deaths, which concern only an undetermined cause of death, are the domain of the work of pathological anatomical autopsy and pathology specialists. Forensic medicine, on the other hand, doctrinally deals with violent deaths (suicides, murders and accidents), unknown and suspicious deaths. Therefore, the focus of the forensic medicine specialist's work, as the name of the specialization suggests, is the work of autopsies that can have repercussions on the legal system. That is, forensic autopsies are performed at the request of the state body - the judicial system, which are the primary users, and they are not performed at the request or suggestion of a doctor. Pathologists perform autopsies that concern the health needs of the system (correct determination of the cause of death is of interest to both the individual and the health system from the point of view of improving the quality of work, planning and organization of the health system, etc.). The approach to the autopsy itself, the autopsy technique and additional diagnostic procedures in forensic and pathologic autopsy are significantly different. While pathologic autopsy focuses on microscopy, forensic autopsy is predominantly macroscopic. Therefore, what already exists in practice in terms of the division of labor for autopsy is the only possible division of labor (which has existed in the Law up to now), that is, which will be improved through the addition of one sentence by the current proposal for changes to the existing Law.

The proposal is accepted

13. Dr. Vladimir Pavićević/Clinic for ENT Clinical Center of Montenegro, submitted a proposal to amend Article 29 paragraph 1 after point 12 to add a new point 13) otorhinolaryngology, and in article 42 paragraph 1 after the word ophthalmology, add the word otorhinolaryngology with the explanation that about a third of examinations in primary health care clinics are patients with symptoms of the ENT region, so the establishment of a special clinic for otorhinolaryngology in the health center would reduce



waiting lists and optimize the referral of patients to secondary care institutions and tertiary level of health care.

The proposal is not accepted

Explanation

Doctors who work at the primary level, specialists in family medicine are educated to provide health services to patients who have symptoms of the ENT region, and by strengthening the primary level of health care, special attention will be paid to additionally educate all selected doctors who work in health centers through continuing medical education to provide health services to patients who have symptoms of the ENT region who work in health centers.

14. Association of Pharmaceutical Technicians of Montenegro, requests that this law stipulates the formation of the Chamber of Pharmaceutical Technicians, and that they be included in the regulated professions.

The proposal is not accepted

Explanation

Bearing in mind the fact that chambers are professional organizations of healthcare workers who organize themselves and form a chamber, in order to improve the conditions for performing the profession and protect professional interests, there is no obstacle to forming it in accordance with the law. The European directive governing regulated professions, with which the national legislation is harmonized, does not recognize the pharmaceutical technician as a regulated profession within the meaning of the EU directive.

15. Lawyer, Miloš Komnenić from Podgorica, in with the submitted suggestions, he proposes that the first step in the registration of a health institution is Central Register of Business Entities registration, followed by registration in the Ministry of Health. He states that in practice the founders of health institutions encounter difficulties because it is difficult to ensure the fulfillment of all the prescribed conditions, given that the entity of the institution itself does not exist at the time of submitting the application for the issuance of a work permit. He suggests that the first step in the establishment of a health institution should be its registration in the Central Register of Business Entities and that the institution itself would not be able to start operating before receiving a decision from the Ministry that it meets the requirements in terms of space, staff and equipment. After registration in the Central Register of Business Entities, the institution would be recognized in legal transactions as an independent entity, submit a request to the Ministry of Health, which would decide in accordance with its competences whether it meets the conditions for work and, depending on that, issue a decision. The very start of work would be subject to the decision of the Ministry of Health. In the event that the Ministry does not find that all conditions prescribed by law have been met, based on such a decision, the institution would be deleted from the Central Register.

The proposition is not accepted

Explanation

The adoption of the proposed solution that the health institution first registers in the Central Register of Business Entities, thereby acquiring an independent entity in legal transactions, would open a wider space for abuses and the provision of health services



without the Ministry's decision on the fulfillment of the conditions in terms of space, staff and equipment.

16. Katarina Badnjar Pharmacist from Podgorica, submitted suggestions to more closely define the pharmacy as a health institution and the conditions under which it provides services.

The proposal is not accepted

Explanation

Pharmacy activity is regulated by the Law on Pharmacy Activity and the Guidelines for Good Pharmacy Activity. In the following period, amendments to the Law on Pharmacy Activity will be initiated, which will regulate this area. In accordance with the law, new by-laws will be adopted that will more closely regulate the conditions for opening this type of health care facility.

That Article 97 is discriminatory and should be corrected in the sense that the general term healthcare worker with a degree in pharmacy should be used.

The proposal is not accepted.

Explanation

The provision is precisely defined and there is no room for claims that it is discriminatory. Article 139 should be corrected in such a way that in paragraph 4 point 2 a certificate of unemployment from the competent Employment Office of Montenegro is added.

The proposal is not accepted

Explanation

In the process of issuing or renewing a health worker's license, there is no need for a certificate of unemployment to be part of the required documentation.

That private practice be added to Article 107, which regulates the conditions for performing additional work.

The proposal is not accepted

Explanation

Private practice is linked to the person who performs private practice. The article in question regulates additional work for health workers and associates in institutions founded by the state or municipality.

That article 204 specifies the management of medical records.

The proposal is accepted

A precise way of keeping medical records.

17. Tanja Radović, Head of the Accreditation Service of the Accreditation Body of Montenegro, in the submitted suggestions emphasizes the need amend article 238 by adding the paragraph "If the health institution has laboratory facilities, the issuance of certificates must be preceded by their accreditation, by the Accreditation Body of Montenegro, in accordance with a special law and relevant international standards".

The proposal is accepted

18. Group of citizens, Mr. Filip Mihailović, Dr. Danijla Miladinović, specialist in psychiatry; Dr. Vesna Blagojević, specialist in psychiatry; Dr. Boris Ćorić, specialist in psychiatry; Dr. Milka Bulatović Nišavić, specialist in psychiatry; Dr. Ana Stanković, specialist in psychiatry; Dr. Neda Grbović, specialist in psychiatry; Dr. Sandra Vlahović,



specialist in psychiatry in the submitted suggestions, they point out that paragraph 5 should be added to Article 83, which would prescribe that the Ethics Committee of the healthcare institution be elected for a period of 4 years, for the reason that it is necessary to have a time limit for the election of the members of the Ethics Committee of the healthcare institution.

The proposal is accepted

- to correct a technical error in Article 113 in terms of alignment with the Labor Law, age as a condition for retirement.

The proposal is accepted

- that Article 128 defines what narrow specialization is.

The proposal is not accepted

Explanation

Professional training is clearly defined by the provisions of Articles 126 to 133, as well as through by-laws. There is no need for additional pre-normation of regulations.

That Article 130 deletes the time limit of two years of work at the primary level for obtaining specialization, as it is limiting for the rapid advancement of young doctors.

The proposal is partially accepted

Explanation

Experience from practice indicates that it is necessary for young doctors to spend a certain period in a health institution in order to gain experience in practice. It was deleted to be work exclusively at the primary level of health care.

To delete the condition for obtaining narrower specialization, work after obtaining specialization for two years

The proposal is accepted

Explanation

Specializations and sub specializations are awarded in accordance with the needs of health institutions and the Specializations Allocation Plan. It is not decisive whether he worked for a certain period in a certain health institution, but what is decisive is the actual need for certain specializations and sub specializations, which is determined by the Annual Plan adopted by the Ministry.

19. Lidija Šćepanović, IPH, in the submitted suggestions proposes to delete Article 18 for the reason that it is not necessary to regulate the content of strategic documents by law.

The proposal is not accepted

Explanation

The article in question prescribes which issues the main strategic document should focus on, and certainly the detailed content and direction of healthcare development are more closely defined by the strategy itself.

To correct Art. 76 and 77 in such a way as to prescribe that a person who has completed basic studies in the field of natural sciences can be elected as the director of the IPH, and that directors in all health institutions are elected through a public competition and on the basis of the submitted program of work and development of the health institution, according to the number of points achieved in the same, in a transparent manner.

The proposal is not accepted



Explanation

That a Public Health Board (instead of a Medical Board) be established in the IPH, taking into account the specificity of the institution, i.e. that public health includes non-medical sciences and areas of research and action from the domains of e.g. statistics, health policy, management, psychology, mental health, chemistry, etc.) and which professions were denied participation in the work of the aforementioned body in the previous solutions.

The proposal is not accepted

Explanation

The law does not prescribe the composition of the Medical Board, but it is prescribed that the composition and number of members of the medical board and the method of their election are regulated by the statute of the health institution. Bearing in mind the above, the statute of the IPH can stipulate that the composition of this body consists of health associates and other persons who can contribute to successful work with their professional references.

In Article 110, make a clear distinction between health associates and non-medical personnel, as well as specify the profiles of personnel who are counted as health associates.

The proposal is not accepted

Explanation

The provisions of Article 109 define that health workers are persons who have an appropriate level of education in the field of health, who, as a profession, perform health care activities and directly provide health care to citizens, in accordance with the law, and Article 110 of the law in question defines that health workers are persons who do not have a health-related education, and participate in the performance of health activities in the field of public health, diagnostics, mental health care, reproductive health care, health care for children and adults with disabilities, early intervention for children with delays and disabilities in development, in accordance with this law.

Bearing in mind the above, there is no room for any ambiguities.

20. Trade union organization IPH, in the submitted suggestions, it is proposed to amend Article 54 point 14 in such a way as to add the words: "and surface and waste waters and basin waters as well as objects of general use"

The proposal is accepted

To amend Article 76 point 1 in such a way as to add the words: "health worker or health associate with a specialization of three years at health-related faculties (medicine, pharmacy, dentistry)" and to add the words: "in addition to social and natural sciences", otherwise, university graduates from natural sciences (Faculty of Natural Mathematics, Faculty of Technology and Metallurgy, etc.) who have been working in health for years are placed in an unequal position.

The proposal is not accepted

Explanation

Requiring that the person elected to be the director of a health institution has a specialization of three years is unsustainable. The jobs of managing a health care institution do not require specialization in a certain field of the person performing the



function of director. It is questionable whether the organization of work and the monitoring of the provision of health services, as well as the application of regulations, financial statements in a health institution can be done by persons who have no education for these jobs during their education at the technical and Faculty of Natural Mathematics.

To correct Article 81 in such a way as to prescribe the composition of the Medical Board as a professional body in a health institution.

The proposal is not accepted

Explanation

The article in question stipulates that the composition and number of members of the medical board and the method of their election shall be regulated by the statute of the health institution.

Article 110 stipulates that health assistants are persons who do not have a health-related education and participate in the performance of health activities in the field of public health, diagnostics, mental health protection, reproductive health protection, health care for children and adults with disabilities, early intervention for children with developmental delays and disabilities, in accordance with this law.

Bearing in mind the above, there is no room for any ambiguities.

That articles 125 and 130 be corrected in such a way as to stipulate that health care assistants can do part of their internship abroad.

The proposal is accepted

Explanation

The traineeship of healthcare associates is regulated by a special regulation. The mandatory condition for the award of specialization is that the health care associate must work for two years at the primary level of health care, but work in a health care institution regardless of the level of health care.

- in Article 134, add the words: "or the commission of the Ministry of Health if the institution of higher education is considered incompetent".

The proposal is not accepted

Explanation

The recognition of a foreign educational document is carried out in accordance with a special regulation. The recognition of specialization, that is, narrower specialization acquired abroad, is not within the competence of the Ministry.

21. DOO HELP, Podgorica, in the submitted suggestions, they point out that it is necessary to define a pharmacy as a health institution.

The proposal is not accepted

Explanation

Pharmacy activity is regulated by a special law, and this law stipulates that it belongs to the type of health institutions.

Article 61 paragraph 2 prescribes what must be submitted with the application for opening a healthcare facility, including the contract for the purchase of equipment, so it is necessary to prescribe that this obligation does not apply to the pharmacy.

The proposal is partially accepted

That in Article 71, paragraph 3, a technical error should be corrected in such a way that the word "midwife" is replaced by the word "pharmacist".



The proposal is accepted

22. Medical Chamber of Montenegro/Commission for Young Doctors of Montenegro, in the submitted suggestions, he proposes to amend Article 129 in such a way as to add a paragraph that would read. "The plan from paragraph 1 of this article is published on the website of the Ministry of Health and the website of institutions founded by the state".

The proposal is accepted

That in Article 130, the specification of two years of work at the primary level of health care as a condition for obtaining specialization be changed and that one year of work in any health care institution be prescribed as a condition.

The proposal is partially accepted

Practice has shown that it is necessary for young doctors to pass basic medicine through practice. The condition, work at the primary level of health care, but work in any health care institution, is deleted. And it remains an exception as a condition for deficit specializations.

That article 130 paragraph 4 prescribes more precisely who bears the costs of specialization, obtaining a license, making a specialist facsimile and that these costs are borne by the body or legal entity for whose needs the specialization is approved.

The proposal is partially accepted

Explanation

The mutual rights of the healthcare institution and the resident are regulated by the contract. In the part of costs for issuing or renewing the license, the proposal is accepted in such a way that the costs will be borne by the competent chamber, because these are transferred jobs and for the same chambers they receive the necessary funds from the state budget. Every year, the Ministry transfers certain funds to chambers for all transferred jobs.

To change the clause in Article 131 that the condition for obtaining narrower specialization is work of two years in the title of specialist.

The proposal is accepted

Article 131 is deleted

The allocation of narrower specialization is done in accordance with the needs of health institutions and the Plan of Specializations and Narrower Specializations.

That Article 132 be corrected in such a way that, as a rule, the public tender is announced twice a year at the same time and unified for all health institutions that would be advertised by health institutions and the same would be announced on the website of health institutions and the Ministry, for the sake of transparency.

The proposal is partially accepted

Explanation

The announcement of competitions for the allocation of specializations is carried out in accordance with the needs of health institutions by health level and the Plan of annual specializations. The proposal to publish the competition for the award of specializations on the website of health institutions and the Ministry is accepted.



That in Article 132, paragraph 4, the words be added: "that the consent to the concluded contract between the health institution and the health worker, that is, the associate, is given by the Ministry.

The proposal is not accepted

Explanation

The contract is an obligatory relationship between entities that have the legal and business capacity to conclude it and there is no legal basis for the Ministry to give consent to it.

That Article 133 paragraph 5 be amended in such a way as to stipulate that the health institution, with the consent of the Ministry, is obliged to offer the doctor of medicine his takeover by another health institution (eg primary level of health care).

The proposal is not accepted

Explanation

Recruiting health workers from health institutions in this way is not legally possible.

That Article 135 be amended in such a way that other forms are added to the form of continuous medical education that would be evaluated in the process of issuing or renewing licenses (scientific projects, papers published in journals) as well as advancement in the profession.

The proposal is not accepted

Explanation

The article in question stipulates that continuous medical education includes continuous monitoring of the development of medical science and the acquisition of new knowledge and skills in order to maintain and improve the quality of health care, not scientific projects, professional articles, reporting adverse effects of drugs, etc.

23. Chamber of Physiotherapists of Montenegro, she proposed to add another paragraph after paragraph 3 in Article 30 ("Health care related to the prevention of..."), which would prescribe that health care in the field of rehabilitation and prevention of injuries and diseases, at the primary level of health care, citizens receive applied physiotherapy through a physiotherapist, according to the instructions of the chosen doctor.

The proposal is not accepted.

Explanation

The chosen doctor, on the basis of the tests performed and the obtained medical documentation, assesses whether the patient needs the health care of a specialist in physical medicine and refers him to further tests and examinations at the secondary level of health care with a specialist in physical medicine. After an examination by a specialist in physical medicine, establishing a diagnosis, the specialist prepares a report and determines further treatment, which includes physical therapy and rehabilitation, when a physiotherapist is involved in accordance with medical protocols. The physiotherapist, again in accordance with the medical protocols, is obliged to act only according to the report of the physical medicine specialist.

In addition to the above, he proposes to amend Article 41, so that the aforementioned article is separated into two articles, and that one article defines health care institutions that provide health care with a focus on support in preserving health, alleviating symptoms



of illness and aiding in daily activities, as well as in accordance with the principles of palliative care. And another article to organize health institutions that provide injury prevention, maintenance of physical well-being and rehabilitation services, considering the focus of physiotherapists' work on maintaining and restoring functional abilities and, as they say, improving the quality of life. They state that the new article should contain provisions that clearly define the possibility of treatment and recovery of the patient.

The proposal is not accepted.

Explanation

In the relevant article in paragraph 1, it will be specified that it is a health institution at the primary level of health care in which health care services and/or rehabilitation are provided. It is clearly defined that patient care is carried out in them. And the application of physical therapy and rehabilitation by a physiotherapist is carried out in accordance with the Report of a doctor of medicine, a specialist in physical medicine.

That Article 97 be amended in such a way as to enable physiotherapists to perform their activities independently at the primary level of health care, and that in the field of health care and rehabilitation, instructions for the application of therapy are not necessary because this condition can be counterproductive in the treatment part. In their statements, they further point out that physiotherapists are not recognized as experts capable of making clinical decisions independently within their field of work, which is not in accordance with international standards.

The proposal is not accepted.

Explanation

The allegation that physiotherapists are not recognized as an important link in the provision of health services is unfounded. On the contrary, in the health system, physiotherapists are an important link in the rehabilitation of patients. Their expertise in that part of health services is indisputable. The requirement that physiotherapists independently make clinical decisions in the treatment of a patient conflicts with the medical profession. According to medical standards, a doctor of medicine, a specialist in physical medicine, establishes a diagnosis based on all medical examinations, prepares a medical report and determines the further treatment of the patient, prescribes the types of exercises and the application of appropriate physical treatments that must be carried out in order to achieve successful treatment and rehabilitation. Physiotherapists are educated for the application of physical therapy determined by a specialist in physical medicine.

To amend Article 109, which defines health workers, in order to regulate it more precisely

The proposal is not accepted.

Explanation

The definition of health workers is given precisely in accordance with the level of education and with positive regulations.

To supplement paragraph 1 in Article 110 by listing the professions from Article 109 that can receive the title of primarius under the conditions prescribed by the Ministry.

The proposal is not accepted.

Explanation



The title primarius is related to titles in the field of medical sciences that have appropriate specialization and for which it is necessary that specialists have a certain experience in the specialist title. In our system, there are no specializations in the field of physiotherapy. The Chamber of Physiotherapists states in its suggestions that physiotherapists are not recognized in the first way by this law. They point out that they are sufficiently educated to be able to provide treatment services independently, and that the principles of providing health services stated in this law and social concern for health (Articles 3, 10, 15, 29) cannot be adequately implemented if it is not regulated normatively that physiotherapists can treat patients independently. These allegations have no basis in medical science. It has already been stated before that physiotherapists at the appropriate level of education are recognized as an important link in the chain of providing health services at all levels of health care, but only medical doctors, physical medicine specialists are educated to establish a diagnosis and determine therapy for the patient, and physiotherapists are involved in the rehabilitation process, in such a way that they conduct physical therapy with the patient, perform appropriate exercises in the manner and to the extent determined by the specialist physiatrist.

24. Medical Chamber of Montenegro, in the submitted suggestions, he points out that Article 2 does not properly define the concept of health care, because it is not an activity but "a system of social, group and individual measures, services and activities for the preservation and improvement of health, prevention of diseases, early detection of diseases, timely treatment and health care, rehabilitation and palliative care."

The proposal is accepted

Delete Article 67, with the explanation that Article 9 stipulates that the guaranteed right to health care "based on the highest possible standards and achievements of modern medical theory and practice" and Article 11 the right to "equal conditions for the provision of health care" is Article 67, which prescribes "special conditions for the provision of health care" in direct conflict with Art. 9 and 10 and that this provision is discriminatory in terms of access to health care.

The proposal is not accepted.

Explanation

Article 67 stipulates that a health institution founded by the state or municipality can offer citizens, within the established standards, special health protection conditions in terms of personnel, accommodation, care and time, according to the opinion of the Ministry, in which case the patient bears the costs of such provided health services. In this way, it is possible for the health institution, if it can provide health services that are not covered by the mandatory health insurance, to do so. The scope of health services covered by mandatory health insurance is in any case provided under equal conditions, respecting the standards and achievements of modern medical theory and practice. The scope of health services is guaranteed, as is the quality of the services.

There is no discrimination in the article defined in this way. It is possible for the health institution to provide special health services to citizens who wish to do so, which are not included in the package of mandatory health insurance services, and are ready to bear the costs for this service themselves.



That Article 77 be amended in such a way as to more precisely prescribe the conditions for the selection of directors of health institutions founded by the state and to create a basis for the adoption of a special act that would determine the criteria for the procedure for appointing and dismissing directors of health institutions founded by the state. The process of appointing and dismissing directors should be made transparent so that it is based on objective criteria, which reduces the possibility of abuse.

The proposal is not accepted.

Explanation

The position of the Ministry is that this article should not be changed, that it should remain the Minister's discretion to choose and propose collaborators with whom he will cooperate and thereby assume full responsibility for the functioning of the health system. The fact that the prescribed obligation of the director to submit a report on the work of the health institution to the Ministry excludes the possibility of abuse. Submitting the Work Report makes his work transparent. The provisions of Articles 76, 77, 78 and 79 prescribe the conditions for the appointment of directors of health institutions founded by the state or municipality, the conditions for the appointment of directors, the director's competencies, obligations, as well as the conditions for dismissal, and there is no place for this issue to be regulated by a separate by-law.

That in Article 93, the term "hospitality establishment" be replaced by "companies performing health care activities"

The proposal is not accepted.

Explanation

The member will be corrected in another way. Businesses cannot provide health care services.

Art. 96 to 101 to be deleted

The proposal is not accepted.

Explanation

The articles in question prescribe the performance of private practice, who can perform it and under what conditions, and the types of private practice. There is no single reason for this form of health care provision. Experience in the countries of the region and beyond recognized this form of providing health services much earlier. Thus, under the prescribed conditions, a private practice can be established as: a clinic (general, specialist and narrowly specialized, health care and/or rehabilitation clinic, laboratory, dental laboratory, pharmacy. A private practice can be established by a health worker who has completed appropriate integrated academic studies in the field of health, in accordance with the law, as well as a health worker with an appropriate higher or secondary education in the field of health, in accordance with the law. The law stipulates that a health worker can establish only one All activities are related to a natural person who establishes a private practice and is registered as an entrepreneur and not as a legal entity.

The Medical Chamber, in the submitted suggestions, requests that the law explicitly prescribe whether doctors who are on old-age pension can be "carriers of activity", i.e. that specialist or narrowly specialist activity of a health institution can be registered on the same. The Labor Law stipulates that the employment relationship ends by force of law for a person who has reached the age of 66.

Clarification



The introduction of private practice gives an opportunity to a healthcare worker who is not employed, or does not perform other independent activities **or is a beneficiary of an old-age pension so that he can independently practice in private practice, under the prescribed conditions.**

That a new article should be added after Article 104 that would prescribe the way of organizing work and determining the schedule of working hours in a healthcare institution, because such an important issue should be regulated by law and not by a by-law.

The proposal is not accepted.

Explanation

The method of organizing work and determining the schedule of working hours is determined according to the type of health care institution, i.e. private practice, and is a matter for a by-law.

To correct Article 107, which regulates the supplementary work of healthcare workers and healthcare associates, and to delete paragraph 4.

The proposal is partially accepted

Explanation

The restriction on performing additional work is deleted, but not the obligation to comply with the conditions under which additional work is allowed.

To delete Article 120, which prescribes the prohibition of receiving money and gifts in the performance of business, with the explanation that there are no mechanisms on the basis of which the value of an individual gift can be determined.

The proposal is not accepted

Explanation

The provision expressly prohibits the receipt of money, securities and precious metal regardless of their value. For individual gifts of small value, it is not controversial to establish an assessment mechanism.

That Article 143 stipulates that the license is permanently revoked in the disciplinary proceedings before the Chamber in the case of serious criminal offenses that make the member unworthy to practice the medical profession.

The proposal is accepted

In Article 139, prescribe that the Chamber can extend the license to foreign citizens until the end of the license period of seven years, which is counted from the day of the first issuance of the temporary license. Also, it is necessary to prescribe that the Chamber replaces the license, as well as issue a duplicate license, with the explanation that it is necessary to establish an institute of license extension for foreigners by law, as those who extend their stay on an annual basis, as well as foreigners with permanent residence who are issued a permit for 5 years, given that the license is issued for the period of validity of the residence permit. In this way, it would be possible for the rules related to license renewal to be applied equally to all members of the Chamber, regardless of their citizenship.

The proposal is accepted

In Article 146, add that in addition to the aforementioned tasks, the Chamber performs the following tasks:

- extends licenses,
- issues duplicates and replaces licenses,



- keeps the list of members of the Chamber,
- keeps records of accumulated points in the framework of continuous medical education necessary for renewing the license of its members,
- conducts disciplinary proceedings.

The proposal is accepted under indent 1, 2 and 4.

The Medical Chamber proposes that this law prescribes that the status of a narrow specialist is recognized for a specialist doctor in cases where a specialist doctor in Montenegro has been performing the tasks of a narrow specialist for a long period of time, because in most cases there was no formal education for certain narrow specializations, and that doctors in the surrounding area (Croatia, Serbia, Bosnia and Herzegovina, Macedonia) with the same work experience and degree of qualification are recognized as a narrow specialist, and that this issue be resolved in a similar way in Montenegro. With the adoption of the proposal, doctors who have been assigned to narrow specialist jobs for a long period of time will receive legal protection and satisfaction, and the institutions will legally to regulate the transition period from one to another method of education of specialists and narrow specialists.

The proposal is accepted and will be arranged in such a way that the status of specialist can be acquired by a specialist doctor in a certain field of health care, i.e. a branch of medicine who has performed practical specialist health care in a health institution for at least 10 years, before the employment of the first specialist doctor for that area of health care, i.e. a branch of medicine and who has completed training and education according to a special program for that area, i.e. a branch of medicine. The Faculty of Medicine, with the prior opinion of the competent chamber and the consent of the Ministry, decides on the removal of the status of junior specialist, based on the request. Closer conditions and determination procedure

the narrow specialist will be prescribed by the Ministry.

To delete articles 151 to 188.

The proposal is not accepted

Explanation

On its way to the EU, Montenegro has the obligation to harmonize national legislation with EU regulations. For the aforementioned members, national legislation was harmonized with the European regulation Directive 2005/36/EC of the European Parliament and the Council of September 7, 2005 on the recognition of professional qualifications with all the annexes that amended this directive.

To delete articles 196 to 198, which regulates the application of complementary medicine, with the explanation that the methods and procedures of complementary medicine are not based on scientific or expert evidence of effectiveness, and that it is unclear who determines the standards of complementary medicine. It slows down the application of alternative methods and procedures in practice, and the mentioned articles should be deleted, because there is no evidence of the usefulness of these methods and procedures

The proposal is not accepted

Explanation

The use of alternative methods and sub-treatments, i.e. complementary medicine, is not new and is represented in all surrounding countries and beyond. Strict conditions for application are prescribed. Thus, expertly verified traditional and complementary methods



and procedures of prevention, diagnosis, treatment, health care and rehabilitation can be applied in the provision of health care. ***which are not covered by the methods and procedures of conventional medicine, and which: do not harm health, do not deter the patient from using the methods and procedures of conventional medicine, and are performed in accordance with the recognized standards of complementary medicine.*** It is prescribed that methods and procedures can be performed in a health care institution, other entities that perform health care activities, or private practice, in accordance with this law and the regulations adopted for the implementation of this law, by a health worker who has a diploma or other appropriate proof of an acquired professional title in the field of complementary medicine. The diploma, or proof, must be issued by a recognized international organization for complementary medicine. Exceptionally, the methods and procedures of complementary medicine can be performed by a person who graduated from the faculty of traditional Chinese or Indian medicine for at least four years and obtained the title of doctor of traditional Chinese medicine or doctor of traditional Indian medicine. The methods and procedures of complementary medicine can be performed by a health worker, i.e. a person to whom the Ministry has issued a decision, based on a submitted request for the performance of certain methods and procedures of complementary medicine with the previously obtained opinion of the Commission as a special body established by the Ministry.

That Article 241, which prescribes the time and cause of determining the cause of death, should be corrected because the costs of educating doctors who must be additionally educated to determine the cause and time of death are not shown, and the competence of the Ministry to pass a by-law that will regulate this area more closely, but that this should be done by the Faculty of Medicine or the Center for Forensic Medicine.

The proposal is not accepted

Explanation

Continuing medical education is regulated by a separate article. When it comes to passing a by-law that will regulate the method and content of the education of medical doctors, the number of doctors by municipality, the organization of the working hours of these doctors, the conditions for determining the time and cause of death, the form of the death certificate and medical report is the responsibility of the Ministry, not the Faculty of Medicine or the Center for Forensic Medicine. In the process of drafting regulations, the profession is consulted and experts are engaged in the working body.

The remark that a private-public partnership has not been developed is unfounded. The conclusion of contracts and cooperation with health institutions whose founder is not the state is carried out by the Health Insurance Fund in accordance with a special law.

25. Chamber of Commerce of Montenegro, submitted the suggestions expressed by: **Accreditation body of Montenegro** indicates the importance of the accreditation of medical laboratories according to ISO 15189 in order to ensure compliance with the best European practice and that the chapter regulating the Accreditation of healthcare institutions should be supplemented by the inclusion of the specified standard

The proposal is accepted

An amendment to Article 235 was made, in the way that it is prescribed that, if the health institution in has a laboratory in its composition, the issuance of a certificate on the accreditation of



a health institution must be preceded by the accreditation of the laboratory performed by the Accreditation Body of Montenegro, in accordance with a special law and relevant international standards.

General dental clinic "Montedent" submitted suggestions on articles 30, 36 and 155.

The allegations that there are currently no dental clinics in health centers (Article 30) are indisputable. He states that the previous dental clinics had neither data exchange nor guaranteed connection with health centers, the Clinical Center of Montenegro in terms of data exchange, and the system of automatic recognition is questionable considering that documents are being sought for the re-nostrification of those who were nostrified as early as 2028.

Clarification

With the reform of the health system, dental health care services will return to the public sector, clinics that will be organized in educational institutions but will be connected through health centers

It is indisputable that the current organization of the health sector does not include digitization of the health system and networking of all entities that provide health care. One of the main goals of the health sector reform will be the digitization and networking of all health institutions through the Unified Information System in order to exchange data. The chapter regulating the automatic recognition of professional qualifications is also harmonized with the EU directive as an obligation of Montenegro on the path to accession to the European Union.

The remarks and proposals of the Dental Chamber are explained in advance, given that it independently submitted them to the Ministry.

The Faculty of Medicine submitted suggestions to amend Art. 2 paragraph 2 in such a way that the term "promotion" should be added, so that the paragraph reads "Health care represents a set of measures and activities for the promotion, preservation, protection and improvement of health..." and in Article 8, the meaning of the terms "patient" and "health tourism" should be added.

The proposal is accepted

In the section on health activities, amend Article 29 and add: determining the cause of death, performing health examinations of foreign citizens for the purpose of issuing work and/or residence permits.

The proposal is not accepted

Explanation

Determining the cause of death is not carried out in the health institutions where the person dies. If a person dies outside a health facility, specially trained doctors from health centers are hired. Health examinations of foreign citizens in connection with the issuance of a work and/or residence permit are performed as a service to a third-party appraiser of a health institution.

After Article 33, add a new article that would specifically regulate social medicine services.

The proposal is not accepted

Explanation

Represented through provisions that regulate activities at the primary level of health care, which, among other things, include: improvement of citizens' health, prevention, health



education and education about the most common health problems, promotion of healthy lifestyles including healthy nutrition and physical activity of citizens, health promotion. In Part V ORGANIZING HEALTH ACTIVITIES, Article 53, add that the Institute performs "scientific research activities for the area for which it was founded, which are regulated by the Law on Scientific and Research Activities"

The proposal is not accepted

Explanation

Whether the Institute as a health institution will be a scientific base, i.e. whether it will carry out scientific research activities is determined by several factors

To correct Article 93 paragraph 1 in such a way as to specify that health care services can be provided within the hospitality facility if there is adequate staff, space and equipment and other conditions prescribed by the Ministry are met.

The proposal is not accepted

Explanation

Prescribed by Article 94

That Article 156, paragraph 2, be corrected so that training lasts six years instead of five.

The proposal is not accepted

Explanation

The European directive with which we have to harmonize the national regulation prescribed a period of five years.

Institute for Standardization of Montenegro, amend Article 8 and give the full name of EU DIRECTIVE 2005/36/EC

The proposal is accepted

That in Article 17, paragraph 2, the composition of the commission be deleted because it is prescribed in paragraph 4

The proposal is accepted

That Article 93 paragraph 1 be corrected in such a way as to prescribe that "healthcare services may be provided within the framework of the hospitality establishment."

The proposal is accepted

In Article 152 paragraph 1, state the full name of the directive 2005/36/EC

The proposal is accepted

In Article 195, paragraph 4, correct the reference to the paragraph

The proposal is accepted

Innovation Working Group for Sustainable Health Tourism - Ministry of Education, Science and Innovation, states that it is necessary to give a definition of health tourism. They also point out that there is no regulation in the EU that defines the field of health tourism and that it is up to the states to adopt a national definition of health tourism according to their needs and specifics. In addition to the above, he points out that it is necessary to divide health tourism into medical and wellness/SPA tourism.

The proposal is partially accepted

Explanation

The subject of this law cannot be wellness/SPA tourism services, but a separate regulation

To prescribe that every entity that provides health tourism services must inform the Ministry about it



The proposal is not accepted

Explanation

It is already prescribed that for the provision of health services, including health tourism services, a decision of the Ministry on meeting the requirements regarding space, staff and equipment, Article 94, must be obtained, and the Ministry has official records of the issued decisions.

KV sistem MNE doo, in his statements, he emphasizes the need for a clear definition of health tourism, to define the difference between medical and non-medical services, to precisely define what types of medical services can be part of "health tourism", to prescribe special conditions for their provision, records of facilities, to prescribe standards, form and content of the logo.

The proposal is partially accepted

Explanation

Article 93 of the law in question provides the legal basis for the adoption of a by-law that will regulate the provision of health tourism services as well as prescribing the necessary standards under which health tourism services can be provided.

26. Miloš Čolaković, student trustee of the Faculty of Medicine, in the submitted suggestions, it is stated that Article 130, which regulates the conditions for the award of specialization, should be amended in such a way as to change the condition that for the award of specialization, a healthcare worker must, after passing a professional exam, be employed for two years at the primary level of health care

The proposal is accepted

Explanation

The condition of working for two years at the primary level of health care is deleted, but it is work in any health care institution regardless of the level of health care. Please note that the allocation of specializations and narrower specializations is done in accordance with the needs of health care institutions and the Annual Plan adopted by the Ministry.

27. National Association of Nurses and Midwives of Montenegro, in the submitted suggestions, he points out that amendments should be made to Articles 144 and 145, which refer to chambers as professional associations of health workers, in order to prescribe the organization of the Chamber of Nurses, Midwives and Technicians.

The proposal is not accepted

Explanation

Article 145 stipulates the right that other health workers can also organize the work of chambers. In addition, the Law on Patient Health Care (Article 20) prescribes Yes The Chamber of Nurses, Midwives and Technicians as an independent professional organization that has the status of a legal entity with rights, obligations and responsibilities educates in accordance with the law and the statute of the Chamber.

To amend Article 161 in such a way as to use the term general care nurse, instead of just a nurse, as well as the part of this article related to training in order to comply with Annex V of Directive 2005/36/EC.

The proposal is accepted



To amend Article 163, which refers to the competencies of nurses, in order to bring it into line with the EU directive

The proposal is accepted

28. Medical psychology specialists CCM, Dr sci Nevenka Pavličić, Mr Nebojša Žižić, Mr Mina Gazivoda, Mr Nađa Sevaljević, Mr Olivera Marković, Mr Marko Đurđić, Mr Kristina Bećur, Branka Mitrić, Mr Milena Raspopović, specialist in medical psychology, Ivan Brajković, specialist in medical psychology, Eldina Gusmišević, specialist in medical psychology and Danijela Femić, specialist in medical psychology, in the submitted with suggestions, they point out that their status from the category of healthcare associates should be changed by law to the category of healthcare workers, given that they acquire their specialization at the medical faculty.

The proposal is not accepted

Explanation

Health workers are persons who have an appropriate level of education qualification in the field of health, *who, as a profession, perform health care activities and directly provide health care to citizens, while health care associates are persons who do not have a health-related education*, and participate in the performance of health activities in the field of public health, diagnostics, mental health protection, reproductive health protection, health care for children and adults with disabilities, early intervention for children with developmental delays and disabilities. Acquiring a specialization at the medical faculty cannot be decisive for obtaining the status of a health worker.

29. Association of private medical doctors of Montenegro, in the submitted suggestions, he points out that the definition of "basic life support measures" should be specified in Article 8

The proposal is accepted

Article 13 should be amended in order to more precisely define the obligations of health workers and health institutions when providing emergency medical assistance or other health services, as well as the costs for the services provided.

The proposal is not accepted

Explanation

The aforementioned article precisely defines the obligations of the health worker and the health institution, such as who bears the costs for the service provided to a foreigner. The remark that the provision of health services through a private practice in the sense of this law is not carried out in a health institution, but that the service is provided by an entrepreneur, is extremely tendentious. Article 97 is ignored, which stipulates that private practice can be performed, among other things, in an outpatient clinic, which can be general, specialist or narrowly specialist, and in other types of health care institutions. The difference is in the type of registration, whether the healthcare worker will establish a legal entity or whether he, as a natural person, will register as an entrepreneur and provide healthcare services in his clinic. In the case of private practice, in the sense of this law, the activities are tied to the healthcare worker and they cannot be transferred to another person. Only one private practice linked to a natural person can be registered.



The choice is up to the healthcare worker himself as to how to register, as a legal entity or as a natural person/entrepreneur.

To make a correction in Article 29 in such a way as to change the sequence of activities listed by points, by changing point 14, 15, 16 and 20 should be moved to be points 1, 2, 3 and 4 because they are crucial activities at the primary level of health care as stated in article 28 and 30. All other activities/specialties are actually support and supplement activities.

The proposal is accepted

To amend Article 40 in such a way that, as stated in the current law, outpatient clinics and laboratories are not independent health institutions, but are an integral part of a health institution.

The proposal is not accepted

Explanation

It is indisputable that a health institution can have these types of organizational form in its part. But, as prescribed, they must have appropriate space, equipment and personnel. On the other hand, every entity is given the opportunity to register these types of health institutions. This type of health apartments is most suitable for a health worker to provide private practice services as a natural person in these types of health institutions.

To amend Article 42, which defines the activities carried out in the health center, and to delete the words "provides support"

The proposal is partially adopted

In Article 61, paragraph 2, point 8, it is not acceptable that interoperability is a mandatory condition for the establishment of a health institution, and that point 10 should be deleted.

Prelog is accepted

In Article 78, specify that the report is submitted by the director of the health institution founded by the state.

The proposal is accepted

In Article 83, it is specified in which health institutions must have a code of ethics.

The proposal is not accepted

Explanation

The article in question does not prescribe a code of ethics

Article 96 is unclear in terms of private practice registration and should be amended.

The proposal is partially accepted

Paragraph 2 will be specified in the sense that the opening of a private practice is carried out in accordance with this law, and the detailed conditions will be regulated by secondary legal acts.

To amend Article 119.

The proposal is partially accepted

Explanation

It will be specified in paragraph 3 that the realization of the private interest of healthcare workers, i.e. healthcare associates who work in institutions founded by the state, i.e. municipality.

To clarify articles 129 to 132, whether the allocation of specializations and narrower specializations refers to health workers and health associates who work in health institutions founded by the state or municipality.



The proposal is accepted

Clarification

The allocation of specializations and narrower specializations to healthcare workers, i.e. healthcare associates who work in healthcare institutions founded by the state, i.e. municipalities, is carried out in accordance with the needs of the healthcare institution and the Annual Plan for the allocation of specializations and narrower specializations that the Ministry brings for the needs of healthcare institutions founded by the state.

To amend Article 139 paragraph 4 point 1 or to delete it.

The proposal is not accepted

Explanation

The Ministry, in cooperation with the competent chambers, implements the process of continuous medical education and ensures the provision of the necessary personnel.

That in Article 199 paragraph 2 the services they provide be added with the explanation that if when submitting a request to obtain a decision on the fulfillment of the conditions, a list of services that the health institution will provide is requested, then there is no obstacle for them to be publicly announced individually or collectively, because they have been approved as such by the Ministry.

The proposal is accepted

To check Article 268 which lists the articles with deferred application

The proposal is accepted

Corrected calls to members that have deferred application.

30. Union of Doctors of Medicine, in the submitted suggestions, he points out that in article 10 paragraph 1 point 1 before the word "doctor of medicine and dentistry" add the word "chosen", and in point 10 after the word "insight" add the word "own", and in point 11 after the word: "arbitrarily leaving the health care facility" add the words: "with a previously signed declaration of responsibility". In point 12, after the word "objection", add the words: "to the actions of a healthcare worker, i.e. a healthcare institution"

The proposal is accepted

That Article 12 be amended in such a way that points 1 and 3 are deleted, and point 2 be amended in such a way that the words "and screening" are deleted in point 2, while two new points are added after it that read: "respond to the mandatory screening", respond to the mandatory immunization program" and prescribe a penal provision for violating the provision from point 2.

The proposal is accepted

In Article 18, add a new item that reads: "monitoring and evaluation plan"

The proposal is accepted

In Article 18, delete point 7 and add the following as priority health care measures:

- treatment and prevention of oncological diseases,
- treatment and prevention of cardiovascular diseases,
- prevention of diabetes and obesity

We are of the opinion that a slip was made by referring to Article 18, if we take into account the content of the suggestion and that the priority measures are prescribed by Article 19 of the Draft Law and that Article 19 was meant.



The proposal is accepted in such a way that in Article 19 point 7 the mentioned diseases will be added.

In Article 42, after the words "occupational medicine", delete the words "and sports" and add the words "sports medicine"

The proposal is accepted

Delete Article 67

The proposal is not accepted

Explanation

Article 67 stipulates that a health institution founded by the state or municipality can offer citizens, within the established standards, special health protection conditions in terms of personnel, accommodation, care and time, according to the opinion of the Ministry, in which case the patient bears the costs of such provided health services. In this way, it is possible for the health institution, if it can provide health services that are not covered by the mandatory health insurance, to do so. The scope of health services covered by mandatory health insurance is in any case provided under equal conditions, respecting the standards and achievements of modern medical theory and practice. The scope of health services is guaranteed, as is the quality of the services.

There is no discrimination in the article defined in this way. It is possible for the health institution to provide special health services to citizens who wish to do so, which are not included in the package of mandatory health insurance services, and are ready to bear the costs for this service themselves.

That Article 77 paragraph 1, 2 and 3 be amended because they are unclear and that it be prescribed that the directors of The Clinical Center of Montenegro and IPH are elected through a public competition, which would remove the suspicion that candidates are not appointed based on objective criteria and would avoid the possibility of abuse and political influence when staffing these positions.

The proposal is not accepted

Explanation

The position of the Ministry is that this article should not be changed, that it should remain the Minister's discretion to choose and propose collaborators with whom he will cooperate and thereby assume full responsibility for the functioning of the health system. The fact that the prescribed obligation of the director to submit a report on the work of the health institution to the Ministry excludes the possibility of abuse. Submitting the Work Report makes his work transparent. The provisions of Articles 76, 77, 78 and 79 prescribe the conditions for the appointment of directors of health institutions founded by the state or municipality, the conditions for the appointment of directors, the director's competencies, obligations, as well as the conditions for dismissal, and there is no place for this issue to be regulated by a separate by-law.

In Article 93, replace the term "hospitality facility" with the words: "companies performing health care activities".

The proposal is not accepted

Explanation

The member will be corrected in another way. Health services cannot be provided by a company.

Delete Articles 96 up to and including Article 101



The proposal is not accepted

Explanation

The articles in question prescribe the performance of private practice, who can perform it and under what conditions, and the types of private practice. There is not a single reason for this form of health care provision. Experience in the countries of the region and beyond recognized this form of providing health services much earlier. Thus, under the prescribed conditions, a private practice can be established as: outpatient clinic (general, specialist and narrowly specialized, outpatient clinic for health care and/or rehabilitation, laboratory, dental laboratory, pharmacy. A private practice can be established by a health worker who has completed appropriate integrated academic studies in the field of health, in accordance with the law, as well as a health worker with appropriate higher or secondary education in the field of health. The law stipulates that a health worker can only establish one private practice. All activities are related to a natural person who establishes a private practice and is registered as an entrepreneur and not as a legal entity.

After article 104, add a new article that prescribes the way of organizing work and determining the schedule of working hours in health institutions, because he believes that this issue should be regulated by law and not by a special regulation issued by the Ministry.

The proposal is not accepted

Explanation

The method of organizing work and determining the schedule of working hours is determined according to the type of health care institution, i.e. private practice, and is a matter for a by-law.

In Article 106, add that a healthcare worker after reaching 60 years of age can perform on-call and standby duty upon personal request.

The proposal is not accepted

Explanation

Organization of on-call and readiness of healthcare workers is carried out by internal acts within the healthcare institution.

Article 107 to be amended

The proposal is accepted

The restriction on the right to additional work has been deleted.

Delete Article 120

The proposal is not accepted

Explanation

The provision expressly prohibits the receipt of money, securities and precious metal regardless of their value. For individual gifts of small value, it is not controversial to establish an assessment mechanism.

Article 143 should be amended in such a way as to stipulate that the license is permanently revoked in the disciplinary proceedings before the Commission of the competent chamber in the case of serious criminal offenses that render the health worker unworthy to practice the medical profession.

The proposal is accepted

Amend Article 130 in such a way as to stipulate that specialization can be granted to a clinical doctor who has been employed for two years in a health institution at the



secondary or tertiary level of health care, of which at least 1 year in the specialist field for which he applied, with the previously fulfilled condition of an average grade of 8 (not lower than 8.5). Create a rulebook for awarding specializations that will provide for testing and assessment of skills and predispositions (manual skills for surgeons, empathy test for psychiatrists, etc.)

The proposal is partially accepted

Explanation

Obligatory work in a health care institution at the primary level of health care is deleted, but work in any health care institution at the secondary and tertiary levels of health care is deleted. In any case, specializations and narrow specializations are assigned according to the needs of the health institution and in accordance with the Annual Plan adopted by the Ministry.

Article 132 provides the basis for the adoption of a rulebook that will determine in more detail the criteria for awarding specializations and narrower specializations, as well as the method of awarding them.

That Article 196 up to and including Article 198 be deleted, with the explanation that the methods and procedures of complementary medicine are not based on scientific or expert evidence of effectiveness, and that it is unclear who determines the standards of complementary medicine. It slows down the application of alternative methods and procedures in practice, and the mentioned articles should be deleted, because there is no evidence of the usefulness of these methods and procedures.

The proposal is not accepted

Explanation

The use of alternative methods and sub-treatments, i.e. complementary medicine, is not new and is represented in all surrounding countries and beyond. Strict conditions for application are prescribed. Thus, expertly verified traditional and complementary methods and procedures of prevention, diagnosis, treatment, health care and rehabilitation can be applied in the provision of health care. ***which are not covered by the methods and procedures of conventional medicine, and which: do not harm health, do not deter the patient from using the methods and procedures of conventional medicine, and are performed in accordance with the recognized standards of complementary medicine.*** It is prescribed that methods and procedures can be performed in a health care institution, other entities that perform health care activities, or private practice, in accordance with this law and the regulations adopted for the implementation of this law, by a health worker who has a diploma or other appropriate proof of an acquired professional title in the field of complementary medicine. The diploma, or proof, must be issued by a recognized international organization for complementary medicine. Exceptionally, the methods and procedures of complementary medicine can be performed by a person who graduated from the faculty of traditional Chinese or Indian medicine for at least four years and obtained the title of doctor of traditional Chinese medicine or doctor of traditional Indian medicine. The methods and procedures of complementary medicine can be performed by a health worker, i.e. a person to whom the Ministry has issued a decision, based on a submitted request for the performance of certain methods and procedures of complementary medicine with the previously obtained opinion of the Commission as a special body established by the Ministry.



31. Private healthcare institution Day Hospital Optimal Podgorica, in the submitted suggestions, points out that Article 97 should be amended in such a way that private practice can also be performed in a day hospital.

The proposal is not accepted

Explanation

Private practice within the meaning of this law can be performed by a healthcare worker as a natural person and registered as an entrepreneur. The day hospital is a health institution, a legal entity, and thus it is registered in the Central Register of Business Entities.

Place and date of making the report

Podgorica, January 9, 2025

The name of the organizational unit of the Ministry responsible for the preparation of the draft law

Directorate for Normative Affairs and monitoring the application of regulations in the field of health care

Signature of the minister, that is, the head of the organizational unit of the Ministry responsible for preparing the draft law

Secretary of State
Mr. Mirjana Vlahović, Andrijašević