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NEW LAW ON HEALTH CARE

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On 3 April 2019 the National Assembly of the Republic of Serbia has adopted the Law on Health Care ("Official Gazette of RS", no. 25/2019) (hereinafter referred to as the "Law"), which entered into force on 11 April 2019. The Law regulates the health care system and its organization, social care for health of the population, the general interest and supervision over the implementation of the Law.

Since 2005, when the previous law was adopted, significant changes in social and economic relations as well as the novelties in the health care system have led to the necessity of reforming this area.

The Law stipulates that the right to health care is granted to the citizens of the Republic of Serbia as well as to foreign citizens, persons who have refugee status, persons without citizenship who have permanent or temporary residence in the Republic of Serbia or who pass through the territory of the Republic of Serbia. In comparison with the provisions of the previous law, the circle of persons to whom the right to health care is granted has been extended.

Social care for health is granted to the new categories of population:

- 1. young unemployed persons who are not involved in education, up to the age of 26 years;
- 2. military and civilian invalids of war and other persons with disabilities;
- 3. victims of terrorism;
- 4. persons who spent time in war, refugees, persons expelled from the territory of SFRY, who are unemployed and with a low monthly income and a residence on the territory of the Republic of Serbia:
- 5. persons to whom recommended immunization is provided.

The Law also separates social care for health on the Level of the autonomous province and the social care for health on the level of the local self-government unit. In regard to the social care for health at the individual level, the Law stipulates that an individual is obliged to respond to the call for targeted preventive examinations or screening, pursuant to

the respective national programs.

For the reason of simplification and efficiency of the procedure of implementation of the social care for health on the national level, instead of the previous solution pursuant to which the Health Care Development Plan was adopted by the National Parliament of the Republic of Serbia, the Law prescribes the adoption of the Health Care Development Strategy by the Government of the Republic of Serbia.

The Law introduces the concept of health care provider, which includes:

- 1. health care institutions in public and private property;
- 2. high education institutions in the field of health profession and other legal entities for which a special law stipulates that they perform health care activities:
- 3. private practice;
- 4. health care employees who perform health activities;
- 5. other high education institutions and scientific-educational and scientific institutions, in accordance with the opinion of the Ministry of Health.

Also, the Law introduces the new forms of health care institutions:

- 1. health care institution polyclinic,
- 2. medical center, and
- 3. military medical institution or medical unit and institution of the Serbian Armed Forces.

The establishment of the medical centers will contribute to a better organization of work and better availability of personnel and equipment.

The new legal solution provides that the regulations governing the legal status of the business entities are applied to the bodies of the private health care institution, their status changes, changes in their legal form and the cessation of their existence. This solution will lead to better organization of the private health care institutions.

Also, the Law stipulates that the health care institution can be established in accordance with the regulations governing public-private partnership.

The Law prescribes that the health care institution may engage a health care employee of another specialty from another health care institution or private practice, by execution of the agreement on business and technical cooperation with another health care institution or private practice, or by execution of an agreement on the supplementary work with a health care employee, as well as in other way determined by the law regulating the work of employees in public services, if the cooperation with the said health care employee is necessary for the provision of the safe health care within the health care activity for which the health care institution is established.

This also refers to the engagement of the said health care employee by the specialist medical clinic, polyclinic and the institutions for the execution of criminal sanctions. This could significantly improve the quality of the health care services. Apart from afore mentioned situation, performing of the health care activity other than health care activity determined in the decision on the fulfillment of the prescribed conditions for performing the health care activity of particular health care institution rendered by the Ministry of Health is forbidden.

Pursuant to the provisions of the previous law, health care institutions were registered in the Court Register within the Commercial Courts. One of the most significant novelties is the registration of the health care institution and its organizational unit in the new Register of Health Care Institutions kept within the Serbian Business Registers Agency (hereinafter referred to as the "Register"). The Register will be electronic, central, public database of registered health care institutions that perform health care activities in accordance with the decision on the fulfillment of the prescribed conditions for performing health care activity. This Register will contain data regarding both public and private health care institutions. Serbian Business Registers Agency will also keep the Unique Record of Health Care Subjects (hereinafter referred to as the "Unique Record") for the purpose of complete and unified recording of the data regarding public and private health care institutions on the territory of the Republic of Serbia.

The Register and the Unique Record will be established within 18 months from entering into force of the Law. Within the same deadline, the Serbian Business Registers Agency will take over from the Commercial Courts data regarding the registration of the health care institutions according to the last registration status. However, within three months from entering into force of the Law, the Serbian Business Registers Agency will take over from the Commercial Courts all files, archives and registry materials related to the health care institutions. Also, health care institutions are obliged to submit the application for registration of harmonization in the Register within three months from the completion of the said taking over of the data by the Serbian Business Registers Agency.

Until the establishment of the Register and the Unique Record, health care institutions will be registered in Court Register within the competent Commercial Courts. The Law also prescribes which data and information will be contained in the Register and stipulates their publication on the website of the Serbian Business Registers Agency.

Health care institutions are obliged to harmonize their general acts, organization and activities with the provisions of this Law within 12 months from entering into force of this Law, save for the health care institutions from the Network Plan which will change the founder and which will be obliged to harmonize their general acts, organization and activities within 15 months from entering into force of the Law.

Pursuant to the provisions of the previous law, the private practice could temporarily cease performing of a health care activity for a period not longer than 12 months. However, according to the provisions of the Law, this period cannot be longer than five years. On the other side, private practice pharmacy may temporarily cease performing of a health care activity for a period not longer than 30 days.

In case of temporary cessation of performing the health care activity for a period shorter than 30 days, the founder of private practice is obliged to point out the notification on the temporary cessation of performing the health care activity at the place where the health care activity is performed.

Hence, in this case the Law does not prescribe the obligation of notifying the Ministry of Health, which was stipulated by the previous law. In case of temporary cessation of performing the health care activity for a period longer than 30 days, the founder of private practice is be obliged to notify the Ministry of Health, the Serbian Business Registers Agency and the competent chamber immediately, however within five business days from the 30th day of the temporary cessation of performing the health care activity. Also, the founder is obliged to notify the Ministry of Health, the Serbian Business Registers Agency and the competent chamber on the resumption of the performance of health care activities within five business days as of the said resumption.

Provisions regarding the new health care technology are extended. The Minister issues a license for the use of new health care technology, based on the opinion on the assessment of health care technology, the Minister issues a license for the use of new health technology. The novelty is related to the information contained in the license - conditions for the application of the new health care technology, the level of the estimated risk of harmful consequences for the life and health of patients as well as the level of health care on which the new health care technology is applied. Upon issuance of the license, the new health care technology can be applied in the health care system at the level of health care for which the license has been issued.

Provisions regarding the strike in the health care institutions have been extended. Organizing the strike is forbidden not only in the health care institutions which provide emergency medical care services, but also in the organizational units of other health care institutions that provide reception and treatment of patients in emergency conditions.

The average weekly working hours, with overtime working hours and on-call hours, cannot last more than 48 hours a week during the period of four months. The provisions of the collective agreement can stipulate that the average working hours can be determined for the period longer than four months, however not longer than nine months.

The Law introduces the Center for Disease of Greater Public Health Significance and prescribes its activities. The Minister of Health determines which

health care institutions at the tertiary health care level perform activities of the Center for Disease of Greater Public Health Significance.

The Law also introduces the health care institution polyclinic as the new form of health care institution. The health care institution polyclinic performs health care activities at the primary level of health care and provides specialist-consultative health care activities from at least three different fields of medicine or dental medicine.

It is also prescribed which fields of medicine or dental medicine have to be covered in performing of the health care activities by the clinical hospital center.

One of the novelties in relation to the bodies of the health care institution is the provision pursuant to which in case the director of a health care institution is not a medical professional, the health care institution must have a deputy director who is a medical professional. Also, the qualification and qualities of the health care employees, health care associates, director and other bodies of a health care institution as well as the procedure of appointment of the director are prescribed in more details.

The Law entered into force on 11 April 2019, except the provision of Article 115, paragraph 1, item 2 of the Law, which shall be applied after 36 months as of the entering into force of the Law and shall refer to the certain qualification required for the director of the health care institution.

