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Legal Bulletin

Healthcare Law

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Healthcare reform - the accreditation of healthcare units and the documents attesting the insured capacity

The Government Ordinance No. 11/2015 ("GO No. 11/2015")¹ that entered into force on February 2, 2015, amending Law No. 95/2006 on healthcare reform², provides the dissolution of the National Commission for Accreditation of Hospitals (the "Commission") and its substitution by the National Agency for Quality Management in Healthcare (the "Agency"). In addition, GO No. 11/2015 establishes special provisions regarding the status of persons who expressly decline the acceptance of the national health insurance card for religious or conscience reasons.

The Agency is established by reorganizing the Commission as a public institution with legal personality, being a specialized body of the central public administration system subordinated to the Romanian Government and coordinated by the Prime Minister. The Government decision approving the composition, duties and organization of the Agency will also provide the conditions of the assessment, reassessment, accreditation, re-accreditation and the monitoring of healthcare units and the collaboration between the Agency and the healthcare units seeking accreditation. The above mentioned Government decision will be elaborated within 60 days as of the publication of GO No. 11/2015 in the Official Gazette of Romania, which means that it should be elaborated by March 30, 2015.

GO No. 11/2015 expressly provides that the accreditation certificates issued by the Commission will remain valid.

¹ Government Ordinance No. 11/2015 amending and supplementing Law No. 95/2006 on the healthcare reform, published in the Official Gazette of Romania, Part I, No. 84 / 30.1.2015.

² Law No. 95/2006 on the healthcare reform, published in the Official Gazette of Romania, Part I, No. 372 / 28.04.2006, as further amended and supplemented.

As a matter of novelty, <u>the accreditation</u> is defined as the process of validating the compliance characteristics of the health services performed by healthcare units with the accreditation standards adopted by the Agency. Also, it is provided that in order to enter the accreditation process, healthcare units are required to organize *an internal structure for quality management of the medical services*.

Failure to obtain accreditation within 5 years as of the granting of the functioning authorization of the healthcare unit will not cause <u>dissolution</u> of the healthcare unit, but its <u>impossibility to</u> <u>conclude the contract for the supply of medical services with the health insurance houses.</u>

The evaluation of the healthcare units for re-accreditation may also occur at the initiative of the Agency or at the request of the legal representative of the healthcare unit, and not only at the request of the Ministry of Health, of the National Health Insurance House (NHIH) or of ministries and institutions with individual healthcare network.

GO No. 11/2015 provides that, after the implementation of the provisions on the European and the national health insurance card, the documents attesting the capacity of insured in the social health insurance system will be either:

- The national health insurance card
- or
- The attesting certificate valid for 3 months.

The person who expressly declines the acceptance of the national health insurance card for religious or conscience reasons may prove the capacity of insured in the social health insurance system through the attesting certificate valid for 3 months, a document that will be issued by the health insurance house where the said person is registered and which will have the model established within an order issued by the President of the NHIH. Failure to provide the above-mentioned attesting certificate triggers the payment for the provided medical services, save for the medical services provided for free under a minimum health services package.

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Juca Zbârcea & Asociații offers multidisciplinary services in relation to all relevant healthcare/medical services issues. The firm's lawyers specialising in the applicable regulations affecting the **Healthcare** sector cover regulatory compliance matters (for the service providers, staff, special equipment etc), contractual framework with the Health Insurance Houses, legal matters pertaining to service provider-patient relationship, as well as to the relationship between the medical staff and the clinic/hospital, anti-corruption and deontological matters, special insurance requirements, advertising and promotion rules, mergers and acquisitions, litigation, taxation, as well as assistance in relation to promotion/combat of relevant legislative initiatives. Our clients are healthcare service providers such as clinics, hospitals and laboratories, as well as professional associations of private medical service providers.



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