

## REVIEW AND TRANSPARENCY OF ACCREDITATION AND CONVENTIONING OF PRIVATE FACILITIES

There are many new features in the so-called Competition Decree also in the area of healthcare in terms of (i) rules for the appointment of healthcare managers, (ii) the possibility for manufacturers of generic medicines to apply for marketing before patent expiry and (iii) numerous other issues including important changes for the training of healthcare managers.

Here, we will focus on the revision of the accreditation criteria for healthcare facilities as well as the evaluation of private conventioned providers.

The Competition bill introduces amendments and additions to legislative decree no. 502 of 30 December 1992 (*Reorganisation of the discipline in healthcare matters, under article 1 of law no. 421 of 23 October 1992*), by eliminating provisional accreditation with regard to new applications for convention and reformulating the current article 8<sup>quater</sup>, paragraph 7, in the sense that *"in the case of an application for accreditation by new facilities or for the commencement of new activities in pre-existing facilities, accreditation may be granted on the basis of the quality and volume of the services to be provided, as well as on the basis of the results of activities already carried out, also taking into account the goals of safety in healthcare services"*.

Prior to this legislative amendment, the aforementioned legislative decree no. 502 provided that in the case of an application for accreditation by new structures or for the beginning of new activities in pre-existing structures, accreditation could be granted, on a provisional basis, for the time necessary to verify the volume of activity carried out and the quality of its results, and that any negative verification would lead to the automatic suspension of the provisionally granted accreditation.

Now, instead, the accreditation of new facilities or new activities in pre-existing facilities will be granted taking into account the quality and volume of services, together with the results of any activities already carried out, considering the safety goals of healthcare services and the results of control, supervision and monitoring activities for the purpose of assessing the activities provided in terms of quality, safety and appropriateness.

But there is more. The competition bill also provides that the facilities to be accredited are to be identified *"through transparent, fair and non-discriminatory procedures, following publication by the Regions of a call for tender containing objective selection criteria, which give priority to the quality of the specific healthcare services to be provided"*.

This is not enough: it is also stated that *"the selection must be carried out periodically, taking into account the regional health planning and on the basis of checks on any rationalisation needs of the network under agreement and, for those already holding contractual agreements, on the activity carried out"*.

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And costs will also be subject to comparative evaluation for accreditation, while accredited facilities will in any case be required to *"publish on their website financial statements and data on the qualitative and quantitative aspects of the services provided and on the medical activity carried out by public and private facilities"*.

It is also clarified that failure to ensure the continuous and timely update of the electronic health record (*fascicolo sanitario elettronico*), as well as the results of the control, supervision and monitoring activities for the evaluation of the activities provided, constitutes a serious breach of the obligations undertaken by entering into the agreement.

The following are added to the additional services, not included in the Lea - or in any case integrated with them - and provided by accredited professionals and facilities: primary and secondary prevention services that are not paid for by the National Health Service, Long Term Care - LTC services that are not paid for by the National Health Service, and social services, aimed at meeting the needs of chronic patient, that are not paid for by the National Health Service.

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