

CMS | Romania launches public consultation on secondary legislation on telemedicine

On 5 February 2021, the Romanian Ministry of Health launched public consultations on the draft rules for the implementation of the provisions of Government Emergency Ordinance no. 196/2020 (GEO 196/2020) (also known as Draft Implementing Rules). Annex 1 of the Draft Implementing Rules lists the medical specialisations that can be offered through telemedicine (including, cardiology, several types of surgery, endocrinology or neurology, etc.). Annex 2 describes the general conditions and methods for providing medical services through telemedicine and the responsibilities surrounding provision of these services.

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GEO 190/2020 was adopted at the end of 2020 laying down the general legal framework for the practice of telemedicine in Romania. (An outline of the relevant amendments in GEO 190/2020 can be found here [Romania permanently regulates telemedicine \(cms-lawnow.com\)](https://www.cms-lawnow.com/romania-permanently-regulates-telemedicine)).

Annex 1 of the Draft Implementing Rules lists the medical specialisations that can be offered through telemedicine (including, cardiology, several types of surgery, endocrinology or neurology, etc.). Annex 2 describes the general conditions and methods for providing medical services through telemedicine and the responsibilities surrounding provision of these services.

The types of medical services that can be provided through telemedicine are those described in GEO 190/2020 (see details here [Romania permanently regulates telemedicine \(cms-lawnow.com\)](https://www.cms-lawnow.com/romania-permanently-regulates-telemedicine)). According to the Draft Implementing Rules, these services can be provided in two ways:

- by immediate transmission of information between the healthcare professional and the patient in real time; or
- by exchanging pre-registered medical data, without the need for a real-time presence of the healthcare professional and the patient.

According to the Draft Implementing Rules, patients must know what to expect before making an appointment and paying for the remote consultation or service. In particular, patients must be informed of the following:

- the names and qualifications of the professionals providing the medical services;
- how to contact the doctor;
- the tariffs for the medical act provided by telemedicine;
- details on the technical support service available; and
- the limits of telemedicine services and the possibility for the doctor and the patient to transform the service at any time into a traditional one (i.e. in the office).

The above information must appear on the website, platform or application specifically designed for the provision of telemedicine. Also, patients will need to receive the relevant information (including the tariff of the service) before any interaction occurs. Patients have the right at any time to refuse interaction through telemedicine and opt for the traditional method.

Also, according to the Draft Implementing Rules, ensuring the quality of the telemedicine service is the responsibility of the healthcare and medical units. To this end, healthcare and medical service units will need to comply with certain conditions for the organisation and operation of the telemedicine service, including:

- ensuring the technical conditions for providing the service;
- training for the use of the communication and data transmission systems and platforms;
- compliance with legal requirements regarding the processing of personal data, and the confidentiality and the security of patient health information; and
- securing and keeping all information and documents from the patient or documents resulting from the medical act provided through telemedicine in a physical or electronic file of the patient.

The elaboration of the valuation methodology, as well as the verification of its observance, will be carried out by the National Authority for Quality Management in Health Sector in consultation with the Ministry of Health based on industry standards and relevant local legislation regarding quality assurance in the healthcare system.

From a practical standpoint, it remains to be seen how companies will be able to cope with the challenge of creating secure medical communication platforms that ensure the confidentiality and security of patient-health information. This challenge is considerable, considering that telemedicine is expected to evolve and encompass the medical service provider's access to the patient's electronic file, settlement of these medical services, the issuance of electronic prescriptions and the interoperability of various computer systems, including pharmacies and the National Health Insurance House.

Public consultations on the Draft Implementing Rules will close on 26 February 2021. We are monitoring the legislative process and will update you on any developments in the regulation of telemedicine in Romania.

For more information on Romania's pharmaceutical and healthcare sector, contact your CMS client partner or local CMS expert **Valentina Parvu**.