TELEMEDICINE: A GLOBAL APPROACH TO TRENDS AND PRACTICES

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LAWS AND REGULATIONS ON TELEMEDICINE

1. Is telemedicine allowed in your country? If so, how is it defined?

Telemedicine is allowed in Italy. The Decree of the Ministry of Health of 23 May 2022, No 77, defines telemedicine as 'a method for delivering health and healthcare services at a distance, enabled by information and communication technologies and utilized by health professionals to provide healthcare services to patients and consulting and support services to other health professionals'.

Telemedicine does not replace traditional healthcare services, even in the personal doctor-patient relationship, but supplements these services to improve their effectiveness, efficiency and appropriateness.

2. Please provide a high-level overview of the legal framework regarding telemedicine in your country.

To date, there is no single comprehensive regulation for telemedicine services, but instead various pieces of legislation (eg, decrees and guidelines drawn up by the Ministry of Health). Italian legislation has identified and classified telemedicine services since 2014, with the approval of national guidelines for telemedicine, and the Italian regions issued many regulations on the subject during the Covid-19 pandemic.

An important development for the telemedicine legal framework was the Ministry of Health's National Guidelines for the Provision of Telemedicine Services dated 27 October 2020 (the 'National Guidelines'), which updated the previous guidelines. These guidelines define telemedicine services, and provide rules and standards for their delivery for the purpose of ensuring a minimum degree of uniformity throughout Italy.

In addition to the National Guidelines, many Italian regions have issued their own regulations for telemedicine that establish the requirements and conditions to be met in order for telemedicine services to be reimbursed by their respective regional health services.

Telemedicine is also subject to the following decrees issued by the Ministry of Health:

- Decree of 29 April 2022 that provides guidelines for a 'digital model' for the development of home care;
- Decree of 23 May 2022 that establishes models and standards for home care assistance; and
- Decree of 21 September 2022 that approves guidelines for delivering telemedicine services, further specifying the functional and technological standards, as well as the training requirements for healthcare professionals and users already provided for in the National Guidelines.

All these recent regulations are part of Mission No 6, 'Health', of the National Recovery and Resilience Plan (NRRP) aimed at relaunching the economy after the Covid-19 pandemic and intended to strengthen community-based care and home care.

3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities.

In Italy, there is no specific licensing for telemedicine, only for practising the relevant healthcare profession and/or running healthcare facilities. The bodies with oversight in the medical field,

including for telemedicine, are the Ministry of Health, the regional governments (especially their healthcare departments), local health authorities (azienda sanitaria locale or ASL) and professional associations with healthcare professional members.

Pursuant to Legislative Decree No 502/1992, the provision of healthcare services in public and private facilities must be authorised by the appropriate local authority (upon prior consultation with the region), and certain minimum structural, technological and organisational requirements established by law must be met. In addition, there is a specific accreditation procedure for facilities providing healthcare services funded by the National Health Service (NHS).

Regarding telemedicine services, the Criminal Court of Cassation in ruling No 38485 of 20 June 2019 clarified that the mere collection and transmission of data from patients to healthcare professionals located in a different place does not constitute medical activity and therefore potentially can take place in non-authorised places, including patients' own homes; however, services such as the processing and analysis of data by health professionals constitute medical activity and must take place in authorised health facilities.

Finally, all telemedicine professionals are subject to deontological ethics rules specific to the relevant healthcare professions. Each individual participating in the delivery of telemedicine services must be identifiable through appropriate digital systems and the work performed for each patient must be recorded via computerised systems for the purpose of automated reporting.

4. Was telemedicine authorised during the Covid-19 pandemic?

Telemedicine developed significantly during the Covid-19 pandemic, especially thanks to initiatives undertaken by several Italian regions that provided criteria for services to be reimbursed by the respective regional health services. Further incentive was provided when, in April 2020, the National Institute of Health recommended using telemedicine to treat patients during the health emergency, and then by the National Guidelines mentioned above.

Moreover, the use of telemedicine in clinical trials was regulated by a note on clinical trial management during the Covid-19 emergency issued by the Italian Medicines Agency (Agenzia Italiana del Farmaco or AIFA) on 12 March 2020. That expressly provides for the use of telemedicine in certain trial phases, such as patient monitoring.

5. Is there any possibility of the regulatory landscape being changed in the post-pandemic scenario or has there already been a change in regulation in the post-pandemic scenario?

Although some emergency measures are no longer applicable (eg, the AIFA note on the management of clinical trials during the pandemic), after the crisis ended, the Ministry of Health approved new decrees on telemedicine services that in turn introduced new and updated regulations for home care services. These regulations, part of the implementation of the NRRP, tend to preserve and further develop solutions first implemented during the pandemic.

6. What types of teleservices are allowed (eg, second opinion, teleconsultation, telediagnosis and telesurgery)?

In Italy, the following types of telemedicine services are allowed: (1) televisits; (2) medical teleconsultation (between doctors); (3) remote medical assistance (involving two or more healthcare professionals with different roles and responsibilities); (4) telecare; (5) telemonitoring; (6) telecontrol; and (7) telerehabilitation.

Generally, telemedicine services can be divided into four categories:

1. services that are similar to diagnostic and therapeutic services;
2. services that integrate traditional services;
3. services that support traditional services; and
4. services that can replace traditional services.

7. Who can use telemedicine services? Please indicate whether only doctor-doctor or

also patient-doctor remote medical services are allowed.

Both doctor-doctor and patient-doctor remote medical services are allowed. Indeed, telemedicine services can be used by: (1) patients to prevent, diagnose and monitor conditions, and to provide therapy; and (2) healthcare professionals to exchange information and opinions.

8. Please outline the funding model for telemedicine. Is it available in your jurisdiction's public health system? Is telemedicine under mandatory insurance coverage? Please indicate what legislation applies.

Telemedicine services delivered by public healthcare facilities are financed by the NHS, although agreements with private parties (eg, private insurers) are not excluded. To be financed by the NHS, telemedicine services must meet certain requirements established by each region, as indicated above.

Telemedicine is currently part of Mission No 6, 'Health', of the NRRP, for which €1bn has been allocated.

9. Please indicate whether any insurance requirements are applicable to telemedicine service providers.

To date, there are no specific insurance requirements applicable to telemedicine service providers.

REQUIREMENTS APPLICABLE TO HEALTHCARE PROFESSIONALS AND INSTITUTIONS

10. Who can practise telemedicine in your country? Please indicate whether other healthcare professionals are authorised to provide remote health services under the applicable rules (eg nurses, psychologists, nutritionists and alternative health therapy providers).

There are no specific restrictions regarding healthcare professionals allowed to practise telemedicine. Therefore, they are allowed to do so, as long as they are allowed to practise the corresponding medical activity in person. The National Guidelines for telemedicine issued in October 2020 list – merely as examples and not to be considered as an exhaustive list – the healthcare professionals who can practise telemedicine in Italy: physicians, paediatricians, nurses, midwives, rehabilitation professionals, healthcare professionals in technical-diagnostic and technical-assistance areas, and preventive healthcare professionals.

These guidelines specify that pharmacists and caregivers also may be involved in the delivery of telemedicine services.

11. Are there any specific education requirements or training that healthcare professionals need to meet or attend to provide telemedicine services?

The legal framework regulating telemedicine in Italy requires that each healthcare professional involved in the delivery of home care services be engaged in basic/advanced training programmes to equip them with digital, relational and professional skills, and also to give them access to refresher courses on the use of telemedicine tools. Specific training initiatives will be conveyed through the national platform for telemedicine of the Ministry of Health implemented as part of the NRRP.

In particular, according to the Decree of the Ministry of Health of 21 September 2022, training should be designed to provide participants with the following: (1) basic skills for using computer systems; (2) knowledge of the platform(s) through which services are delivered; (3) telemedicine; (4) knowledge of patient eligibility with regard to specific telemedicine services; (5) skills for interpreting and analysing data from individuals and the target population; (6) skills for remotely managing relationships with patients and other healthcare professionals; and (7) skills for remote communication with patients, caregivers and all members of the healthcare team.

Professionals must also learn about privacy and data security issues related to the use of

electronics.

A service centre or provider centre (facilities involved in the delivery of telemedicine services whose role is discussed in greater detail below) is responsible for the telemedicine education programme.

12. Is there any registration requirement applicable to physicians that provide telemedicine services?

Healthcare professionals involved in the delivery of telemedicine services do not have specific registration requirements, except for those required to be a healthcare practitioner.

13. Please indicate whether special licenses or authorisations are mandatory for institutional healthcare providers engaged in telemedicine services.

Healthcare provider facilities engaged in telemedicine services are public entities or private centres authorised by the regions that comply with regional and national standards for the delivery of telemedicine.

When providers have obtained accreditation from the relevant region (see item 3 above), telemedicine services may be provided at the expense of the regional health service (within certain financial limits), under the conditions set by the region.

Additionally, individual professionals working in private medical practices can deliver telemedicine services, provided that:

1. they are listed in the professional register and are specialists in the medical discipline for which they intend to provide specialised telemedicine services; and
2. they comply with regional and national standards for the delivery of telemedicine.

REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES

14. Are there specific requirements applicable to the telemedicine platform?

As to the minimum requirements and standard of service, the Decree of the Ministry of Health of 23 May 2022, No 77 expressly refers to the applicability of the National Guidelines. In addition, this decree provides that telemedicine platforms that operate at any level – corporate, regional, interregional and/or national – must:

- interoperate with the various national and regional systems supporting healthcare, ensuring compliance with standards for interoperability of data;
- support the integration of organisational processes and structures, albeit with the necessary flexibility to meet specific needs, including overcoming technological fragmentation;
- support the activation of telemedicine services for individual patients;
- standardise interfaces and architecture for the use of telemedicine services, for both the user and professional, with a view to streamlining, user-friendliness and reduction of clinical risk, while integrating with regional/national profiling systems; and
- offer uniform services with high levels of security throughout the entire country that are developed using a modular approach and in compliance with National Guidelines.

15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?

Telemedicine services are delivered through IT infrastructure, which must meet certain electronic requirements.

Such infrastructure must be integrated with the digital health ecosystem and interoperate with the national platform for telemedicine to provide useful data for monitoring telemedicine

utilisation throughout the country and confirm the use of solutions included in the national telemedicine portfolio.

Generally, the tools needed to run and maintain telemedicine services for home care are as follows: devices for recording, storage, and exchange of images, video and data; mobile devices, medical devices and sensors for detecting parameters; and tools that make it possible to connect and consult information across services that contribute to the process of telemedicine.

The collection, storage and consultation of health and social-health information necessary for integrated care at home is achieved using the home record (which contains information on medical acts performed during the home care pathway) and the electronic health record (EHR), that is, the set of health and socio-health digital data and documents generated by present and past clinical events concerning the patient, of which individual medical records are part.

A person's care team may access the service platform and the data contained in clinical records (entered by various professionals and caregivers).

Additionally, for telemedicine services, it is preferable to have a local technical organisation (eg, a service centre or provider centre, see item 11 above) that performs periodic maintenance and, when necessary, resolves the malfunctioning of technological devices and instruments made available to the patient in a timely manner.

According to the National Guidelines for telemedicine, all communications relating to the provision of telemedicine services must be encrypted.

16. Does legislation provide for specific rules concerning patients' medical records?

Data and information relating to the provision of telemedicine services must be recorded in a patient's medical record, physically or electronically, in accordance with applicable regulations.

In addition, all the relevant information for tracking a patient's medical history (eg, exam reports and drug prescriptions) should be included in the EHR created by the Italian regions, which is constantly fed – first and foremost – by doctors and healthcare professionals working in public and private healthcare facilities.

17. Are there geographic location requirements applicable to the provision of telemedicine services?

Telemedicine services can be used by any patient at home, without geographic limitation. The National Guidelines for telemedicine expressly provide that telemedicine services may be delivered in the various Italian regions (and potentially also at the European level). Of course, this requires the regions to handle reimbursements for services delivered to their own patients by other regions.

18. Does the healthcare professional need to obtain the patient's consent to engage in telehealth?

Healthcare professionals must inform a patient about treatment and obtain their consent. Specifically, healthcare professionals must:

- inform patients about treatments and their purposes/results, and the protocols for specific diagnostic and therapeutic plans; and
- obtain informed consent from patients.

With respect to the second requirement, it is necessary to collect patient's consent to engage in telehealth; the consent form must specify the differences with the correspondent in-person activities and the relevant risks (eg, risks associated with a lack of in-person contact and the fact that the doctor will not examine the patient in person, meaning a complete examination isn't truly possible and, in urgent cases, immediate action may be hindered by distance).

19. Is there any other important requirement that should be highlighted?

Doctors should be provided with an individual digital signature certificate to sign the digital report for the telemedicine service, issued by a provider accredited by the Italian Digital Agency (Agenzia per l'Italia Digitale or 'AgID') and usually made available as a smart card or USB token. The technical rules for the digital signing of documents are established by specific AgID guidelines.

DATA PRIVACY ASPECTS

20. Are there data privacy issues that should be considered for the exploitation of such a market? If your answer is yes, please provide a short description.

The processing of data for the purpose of providing telemedicine services needs to comply with the relevant legislation, particularly Regulation (EU) 2016/679 (the 'GDPR'), Legislative Decree No 196/2003 (the 'Italian Privacy Code') and the provisions of the Italian Data Protection Authority.

Patients must be adequately informed of data processing, and the purposes and security measures adopted by the data controller, and provide their consent if required by applicable legislation, including by means of IT tools. Consent is not required if data processing is necessary for the purposes of diagnosis and patient care.

21. Does the applicable regulation provide for criteria and requirements for security systems to protect the patient's information?

The National Guidelines for telemedicine services expressly dictate that encryption systems must be used for the exchange of communications and information between healthcare professionals and patients.

Moreover, specific security measures are provided by AgID for scenarios in which patient information is stored by a public entity in a cloud infrastructure, starting with cloud service providers obtaining ISO 27001 (information security management) certification.

22. Does the applicable regulation provide for requirements for the transfer of information abroad?

Yes, Articles 45 et seq of the GDPR state that transfers of personal data to countries outside the European Economic Area (ie, the European Union plus Norway, Liechtenstein and Iceland) or to international organisations are permitted if the European Commission has determined that those countries or organisations offer an adequate level of protection.

Absent a decision from the European Commission, transfer is allowed when the data controller or processor provides adequate safeguards that equip the data subject with enforceable rights and effective remedies. Adequate safeguards under the GDPR include:

- contractual agreements with the recipient of the personal data, for example, using the standard contractual clauses approved by the European Commission; and
- compliance with a code of conduct or certification mechanism, together with obtaining binding and enforceable commitments from the recipient to apply appropriate safeguards to protect the transferred data.

Finally, if there is a plan to transfer personal data to a third country that has not been subject to a ruling regarding adequate safeguards and appropriate safeguards are lacking, a transfer may be made based on a set of exceptions for specific situations (eg, an individual has explicitly consented to the proposed transfer after having received all necessary information about the risks associated with the transfer).

23. Is there any registration of databases requirement that companies must observe? Are

there requirements regarding the recording of data in the patient's medical records?

There are no specific registration requirements for databases of health data collected as part of the provision of telemedicine services. However, if companies provide cloud storage services of data – including health data – to the public administration (eg, a public hospital), they must undertake a qualification process set up by AgID in order to become accredited cloud service providers, and they must guarantee compliance with the organisational, security, performance and interoperability measures of the infrastructure.

As for recording requirements, at a general level, all operations on personal data intended to be included in the EHR must ensure data confidentiality, integrity and availability. Moreover, the Decree of the President of the Council of Ministers No 178 of 29 September 2015 provides for specific security measures for data storage and access, including: (1) authentication and authorisation systems; (2) selective access; (3) periodic credential verification procedures; (4) traceability of access and operations; and (5) data separation and encryption.

LIABILITIES

24. Please provide a high-level overview of the liability of healthcare professionals and institutions involved in telemedicine practices.

Telemedicine regulations expressly list the following cases of liabilities of healthcare professionals/institutions (as appropriate), that apply specifically to healthcare services delivered remotely:

- liability for determining whether the patient is in a position to be properly assisted through telemedicine services;
- liability for the achievement of set goals; and
- liability for any technical aspects, attributable, for example, to equipment malfunctioning that may affect the delivery of the service.

TELEMEDICINE NUMBERS AND TRENDS

25. Is there any public disclosed information concerning the use and acceptance of telemedicine in your country?

According to the Digital Health Observatory of the Politecnico di Milano, during the pandemic, the use of telemedicine services has increased significantly, facilitating collaboration between professionals and ensuring continuity of care and assistance for patients.

However, by 2021 the use of telemedicine by doctors dropped – with just one in three professionals using digital platforms for doctor-patient communication – although it remains at higher rates than pre-pandemic.

Despite this, interest remains high. Among medical specialists, 47 per cent of the sample used such instruments at least once, up from 34 per cent in 2020. The majority of healthcare professionals and patients would like to use telemedicine services in the future, and investment by facilities is progressively increasing as the NRRP is implemented and related services are regulated by the legislator.

26. What are the perspectives and trends in relation to the matter for the next few years? Please outline any unresolved issues, proposed changes or trends for the telemedicine sector and briefly indicate how these may foreseeably affect medical practice in the near future.

To date, the outlook for the near future appears to be in the direction of an increasing spread of telemedicine services in Italy, the implementation of which is also supported and encouraged at

European level.

Alongside the platforms for interaction between healthcare professionals and patients, we are witnessing a great development of applications and instruments capable of collecting and processing healthcare data, and of connecting and interoperating with such platforms.

Moreover, artificial intelligence is expected to be increasingly used in healthcare and telemedicine, for example, in the context of telemonitoring and diagnostic activities (remote monitoring of vital parameters and early diagnosis of potential health problems) or even in the context of patient engagement strategies and improvement of therapeutic adherence.

For the widespread and homogeneous dissemination of telemedicine in the Italian context, the effective use of resources from the NRRP – especially on the part of the regions in view of their competences in the field of health protection – as well as the completion of instrumental and necessary reforms for telemedicine will be essential.

Another issue concerns the absence of a comprehensive uniform regulation of telemedicine in all the Italian territory because there are many pieces of legislation (ministerial decrees) at national level (together with guidelines) and then several regulations at regional level. For instance, regional competences in the field of health have led each region to set up its own regional EHR 'system', which is often not interoperable with the EHR of other regions, with undeniable consequences also on the provision of telemedicine services (eg, for difficulties in accessing health documents to support telemedicine services by professionals operating in different regions).

In addition, it is unclear to what extent the regulatory framework mentioned above applies to telemedicine services delivered privately because most regulations seem to focus on services to be delivered within the NHS. In the absence of specific provisions, healthcare facilities tend to apply the same rules to privately funded services as well, but clarification in this respect would help in answering some questions often raised by private operators.