

Bird & Bird

Discovering the world of telemedicine

An international overview of the regulatory legislation

October 2022



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Introduction

Background

Telemedicine has been available to healthcare providers for several years. However, it was not until quite recently that the field of telemedicine really took off due to the rise of the COVID-19 pandemic. With the new standard of social distancing and the burden on the healthcare system, the COVID-19 pandemic forced rapid implementation of telemedicine in day-to-day practice, resulting in the use of technology to provide healthcare growing significantly.

Given the necessity of providing healthcare services at a distance, several countries have implemented (temporary) legislation or guidance relaxing regulatory barriers of telemedicine. Although telemedicine might have taken a great leap forward due to the COVID-19 pandemic, this shift in healthcare will leave a lasting impression even after the pandemic has passed.

Telemedicine is a way to provide healthcare using information technology and telecommunications to overcome distance, involving at least two actors, of which at least one is a recognised healthcare provider. Telemedicine refers specifically to remote clinical services.

Europe

According to the European Commission, telemedicine is defined as *“the provision of healthcare services, through the use of ICT, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients”*.

As a healthcare service, telemedicine should be included in the scope of Articles 56 and 57 of the Treaty on the Functioning of the European Union (TFEU) and as a service, telemedicine should be subject to the general freedom regarding the free movement of services.

Since telemedicine is simultaneously a healthcare service and an information service (i.e. a service normally provided for remuneration, remotely and by electronic means at individual request), the following

European legal framework may apply: Directive 2011/24/EU, concerning the application of patient’s rights in cross-border healthcare; Regulation (EU) 2016/679 and Directive 2002/58/EC, concerning data protection; Directive 2000/31/EC and Regulation (EU) 2019/1150, concerning information society services and online intermediation services.

Finally, since healthcare services and the practice of medicine are not entirely harmonised at European level, the provision of telemedicine services may be regulated differently from one member state to another.

For this purpose, we have provided a regulatory overview for the following European countries:

- France
- Germany
- Italy
- The Netherlands
- Poland
- Spain

Non- EU Countries

As telemedicine is characterised by the boundaries encompassing national law, we have also provided a regulatory overview for the following non-EU countries:

- Australia
- United Kingdom

This overview is intended to summarise the national developments and legal frameworks with regard to telemedicine in order assist our clients in understanding their position. This document does not constitute legal advice, if you require more information please feel free to reach out to the country contacts in this document.

Australia

1. What local regulations are in place in respect of telemedicine?

Telemedicine is not directly regulated in Australia. In late 2020, the Minister for Health and Aged Care Greg Hunt, announced plans to implement a universal telehealth system in Australia. However, this initiative has not yet been progressed.

The Health Practitioner Regulation National Law (National Law), which provides the general regulatory framework for all types of regulated health practitioners, makes no specific reference to telemedicine. Telemedicine is indirectly regulated by limitations on access to government funding at a Federal level and through prescribing and dispensing regulations in each State and Territory.

Electronic prescribing (E-Prescribing) was introduced by the Federal Government through amendments to the National Health (Pharmaceutical Benefits) Regulations 2017 in 2019 as an alternative to conventional paper-based prescriptions. It was identified in

the 2018-2019 Federal budget as a priority to improve efficiency, compliance, safety and data collection and forms a key part of the National Digital Health Strategy, which aims to provide paper-free medication management by 2022. All States and Territories now allow electronic prescriptions through amendments to prescribing regulations in each jurisdiction.

In response to the COVID-19 pandemic, the Australian Government implemented the National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020 (PBS Special Arrangement).

The PBS Special Arrangement temporarily implemented measures to provide easier access to pharmaceutical benefits (government

subsidised medicines) from prescriptions made through telemedicine consultations, including the use of digital images of hard copy prescriptions. The PBS Special Arrangement will be repealed on 30 September 2021, unless extended.

2. Are healthcare professionals allowed to provide services through Telemedicine?

Guidelines issued in 2012 by the Medical Board of Australia, emphasised that health practitioners must ensure the “Good Medical Practice: A Code of Conduct for Doctors in Australia” is complied with in relation to any telemedicine service. In July 2020, the Australian Health Practitioner Regulatory Agency (AHPRA) issued updated telehealth guidance in response to the COVID-19 pandemic. The guidance states that any type of health practitioner (including doctors, dentists, pharmacists, physiotherapists, nurses etc) may provide telemedicine services provided it is safe and clinically appropriate. As a result, there is no restriction on the provision of privately funded telemedicine services.

Many healthcare services in Australia are subsidised by the Federal Government, through Medicare Australia. Specific healthcare services which are eligible to receive government subsidies through Medicare are specified in the Medicare Benefits Schedule (MBS). As a result, the inclusion or exclusion of a particular type of healthcare service on the MBS provides a de facto restriction on providers.

3. What types of Telemedicine services are provided (e.g. store-and-forward; remote monitoring; real-time interactive services) and under which conditions is it possible to provide services in Telemedicine mode?

Temporary MBS items were introduced on 13 March 2021 in response to the COVID-19 pandemic to provide a general exception allowing healthcare professionals to offer telemedicine services where there is an existing clinical relationship with the patient, as well as several other specific exemptions.

An established clinical relationship generally requires the patient to have attended at least one face-to-face consultation at the medical practice in the last 12 months.

From 1 July 2021 specific exemptions made government funded telemedicine services available for homeless people, urgent after-hours services, children under 12 months old, patients of Aboriginal Medical Health Services, services relating to blood borne viruses, sexual and reproductive health, pregnancy counselling and

people living in areas where movement is restricted in response to COVID-19. These services can be provided whether or not there is an existing clinical relationship.

These exemptions are due to end on 31 December 2021, unless further extended.

Medicare funded telemedicine services are generally limited to real time video conference consultations. However, under the exemptions discussed above, providers are able to offer telephone consultations in some circumstances, where clinically appropriate.

4. What are the requirements for the advertising of Telemedicine services?

Telemedicine services fall within the definition of a “health service” in the National Law. As such, the advertising of telemedicine services must comply with the advertising requirements set out in section 133 of the National Law. This requires that advertisements for telemedicine services or for a business that provides telemedicine services must not:

- be false, misleading or deceptive or is likely to be misleading or deceptive; or
- offer a gift, discount or other inducement to attract a person to use the service or the business, unless the advertisement also states the terms and conditions of the offer; or
- use testimonials or purported testimonials about the service or business; or
- create an unreasonable expectation of beneficial treatment; or
- directly or indirectly encourage the indiscriminate or unnecessary use of telemedicine services.

Failure to comply with this requirement may result in a fine of up to \$5,000 for individuals and \$10,000 for corporations.

5. Are there local laws regulating reimbursement for services through Telemedicine?

There are no specific laws regulating the funding of telemedicine in Australia.

With the exception of the temporary MBS items introduced in light of the COVID-19 pandemic, currently telehealth services are not generally eligible for Medicare funding. Medicare funding

is available for video consultations by specialist and consulting physicians to patients who live outside of major cities and are at least 15 km from the specialist. Funding is also available for telehealth consultations with patients in residential care facilities regardless of where they are located.

6. *Are there any incentives (also fiscal benefits) promoting telemedicine or the digitalisation of health services?*

As part of the Federal Government's 2021-22 Budget, Minister Hunt announced an allocation of over \$114 million to fund telehealth until the end of 2022.

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France

1. What local regulations are in place in respect of telemedicine?

In France, the area of telemedicine has experienced progressive and exponential development over the years and continues to evolve. Thus, an entire legal framework is dedicated to telehealth under articles L. 6316-1 and seq. and R. 6316-1 and seq. of the Public Health Code (“**PHC**”).

Telemedicine was defined and regulated for the first time by [Law no 2009-879 of 21 July 2009](#) (“*loi HPST*”) that introduced article L. 6316-1 of PHC¹, followed by articles R. 6316-1 and seq. of PHC that define the five different categories of activity covered by telemedicine, along with their implementation conditions.

Although legally defined, telemedicine was not implemented before the [2014 Social Security Financing Law of 23 December 2013](#) provided a first experimental framework of telemedicine for a period of five years, in nine regions before being extended to all of the French territory.

The [2018 Social Security Financing Law of 29 December 2017](#) put an end to the experimentation of telemedicine and made teleconsultation part of the general framework for the reimbursement of medical acts by health insurance (“*Assurance maladie*”). Besides, the experimental program was renewed for tele-monitoring (“*télésurveillance*”) which is still under experimentation today. In 2019, tele-expertise, was also made reimbursable by health insurance.

In 2019, France went through a new development step of telemedicine with [Law no 2019-774 of 24 July 2019](#) that introduced two new concepts: telehealth (“*télesanté*”) and telecare (“*télésoin*”) with telehealth being the combination of both telemedicine and telecare (developed under question 3).

Lastly, the area of telemedicine has experienced spectacular growth due to the COVID-19 pandemic, which has resulted in fast development of the regulation, notably by easing the conditions for the practice of telemedicine and by accelerating the adoption of measures for the implementation of telecare.

2. Are healthcare professionals allowed to provide services through Telemedicine?

In France, healthcare professionals are organised in three categories under French law:

- **Medical professionals:** physicians, midwives, and dental surgeons (articles L. 4111-1 to L. 4163-10 of PHC);
- **Pharmacists** (articles L. 4211-1 to L. 4252-3 of PHC);
- **Paramedical professionals** (nurses, physiotherapists, podiatrists, ergotherapists and psychomotor therapists, orthophonists and orthoptists, medical electroradiology manipulators and medical laboratory technicians, audioprosthodontists, opticians, orthoprosthodontists and orthotists, epithesists, dieticians), **nurses’ aids, childcare assistants, dental assistants, and ambulance drivers** (articles L. 4311-1 to L. 4394-3 of PHC).

¹ [Decree no 2010-1229 of 19 October 2010](#)

Telehealth services are divided into two categories based on the healthcare professionals who carry out these activities:

- **Telemedicine**, for activities performed remotely by a medical professional (article L. 6316-1 of PHC);
- **Telecare**, for activities performed remotely by a pharmacist or by a paramedical professional (article L. 6316-2 of PHC)

Thus, according to these legal definitions, only medical professionals, pharmacists and paramedical professionals might provide telehealth services to the exclusion of nurses' aids, childcare assistants, dental assistants and ambulance drivers.

3. What types of Telemedicine services are provided (e.g., store-and-forward; remote monitoring; real-time interactive services) and under which conditions is it possible to provide services in Telemedicine mode?

The term telehealth (“*Télesanté*”) was introduced to refer to all healthcare services offered remotely through digital technology such as care, consultation, assistance etc, carried out either between healthcare professionals or between healthcare professionals and their patients. As stated above, it covers **telemedicine** and **telecare**.

Telemedicine

Article L. 6316-1 of PHC defines telemedicine as a remote medical practise using information and communication technologies, that allows a medical professional:

- to establish a diagnostic;
- to ensure, for a patient at risk, a preventive or post-treatment follow-up;
- to request a specialised medical advice;
- to prepare a therapeutic decision;
- to prescribe health products or medical services (and to perform these last);
- to perform a telemonitoring of a patient's condition.

Thus, telemedicine is sub-divided in five different medical activities (Article R. 6316-1 of PHC):

- **Teleconsultation**: when a physician (general practitioner or specialist) offers a consultation remotely through video transmission. The professional can assess the patient's state of health and decide which action must be taken;
- **Tele-expertise**: allows a medical professional to seek the opinion of one or more other colleagues remotely by digital means regarding one particular patient;
- **Tele-monitoring** (“*Télesurveillance*”): allows a medical professional to remotely interpret health data necessary for the medical follow-up of a patient. The recording and transmission of data may be automated or carried out by the patient himself or by a health professional;
- **Tele-assistance**: when a physician assists a colleague remotely in carrying out a procedure (either medical or surgical);
- **Medical response**: carried out by the 15-Centres (“*SAMU*” - Urgent Medical Aid Service), it enables a first medical response to be provided remotely and the patient to be guided through the care process.

Telecare

Article L. 6316-2 of PHC defines telecare as a remote practice of care using information and communication technologies and connecting patients with a pharmacist or a paramedical professional.

During the Covid-19 pandemic, telecare was set up progressively for some categories of professional only as a derogation and as an emergency measure, to enable the continuity of care during the health crisis. Recently, it has been made permanent and extended to all pharmacists and paramedical professionals, beyond the period of the state of health emergency². Telecare is now allowed for all activities remotely exercised by a pharmacist or a paramedical professional to the exclusion of care requiring direct face-to-face contact between the professional and the patient and care requiring specific equipment not available to the patient.

Conditions under which telehealth services are provided

Article R. 6316-2 and seq. provides conditions for the practice of telehealth, and specify in particular that each telemedicine or telecare activity is carried out under conditions that guarantee:

- The relevance of the use of telemedicine or telecare assessed by the healthcare professional that should refer to the High Health Authority (“HAS”) guidelines;
- The authentication of the healthcare professionals involved in the procedure or activity;
- The identification of the patient;
- Access by healthcare professionals to the patient’s health data required to perform the procedure or activity;
- When the situation requires it, the training or preparation of the patient for the use of the telemedicine or telecare device;
- The appropriate filing by healthcare professionals in the patient’s medical record (date, report, medical prescriptions).

Besides, the HAS issued guidelines giving further details on the conditions for carrying out telemedicine and telecare in order to guarantee their quality and safety (detailed under question 7).

Moreover, additional conditions exist for the reimbursement of teleconsultation and tele-expertise via health insurance (detailed under question 6).

4. What are the requirements for the advertising of Telemedicine services?

There is no specific law regulating the advertising of telemedicine/ telecare services. However, telemedicine/telecare are a form of medical practice like any other, therefore all the deontological rules of patient care apply.

It must be emphasised that “*medicine should not be practiced as a business*” pursuant to article R. 4127-19 of PHC that also prohibited, until recently, any direct or indirect advertising of healthcare services. However, rules applicable to physicians in terms of information and advertising have been amended and softened with [Decree no 2020-1662 of 22 December 2020](#) that removed the ban on advertising and replaced it with a principle of free communication within a specific framework. Indeed, if practitioners can now communicate more about their activity, including through a website, they are prohibited from calling on the testimony of third parties and from making comparisons with other doctors or establishments (article R. 4127-19-1 of PHC).

5. Are there local laws regulating reimbursement for services through Telemedicine?

Since 15 September 2018, teleconsultations have been made reimbursable via health insurance³. Since 10 February 2019, tele-expertise procedures are also reimbursed⁴. Generalisation of

² [Decree no 2021-707](#) and [Order of 3 June 2021](#) of the Minister of Health, issued after the opinion of the High Health Authority

³ [Amendment no 6 of 10 August 2018 of the national medical convention](#)

⁴ [Order of 16 August 2018 completing the amendment no 6 of the national medical convention](#)

reimbursement of tele-monitoring will also be put in place according to the Social Security Financing Law project for 2022 as from the 1 July 2022.⁵

To benefit from health insurance reimbursement in France, several conditions need to be met⁶:

- Teleconsultation is initiated by a physician of the patient in its coordinated care plan (its personal permanent treating physician, general practitioner or specialist)
- The doctor must have physically seen the patient during a physical consultation (in the office, in a health centre or at home) within the last 12 months.

However, exceptions are provided in the following situations:

- patient is under 16 years old;
- emergency situations;
- doctor is a direct access specialist (gynaecology, ophthalmology, stomatology, oral or maxillofacial surgery, psychiatry or neuropsychiatry and paediatrics);
- patient does not have a treating physician, or if their treating physician is not available within a timeframe compatible with their state of health.

During the COVID-19 crisis, the French government enacted several measures in context of the state of health emergency. First, the requirements above were waived for patients who were COVID-19 positive or those that presented symptoms of COVID-19. These patients could go directly to any doctor for teleconsultation and have the related costs reimbursed through health insurance⁷.

Another measure made teleconsultations, and telecare procedures completely reimbursable by health insurance, as opposed to the reimbursement rate of 70% for classical consultations. This specific measure remained in force until 31 December 2021⁸

6. *Are there any incentives (also fiscal benefits) promoting telemedicine or the digitalisation of health services?*

In France, telemedicine was conceived as a possible solution to major public health issues such as the difficulties of access to care in certain areas, the lack of medical personnel and the limits encountered by isolated establishments physicians. Also seen as a mean to save on health insurance as offering remote services would simplify access to care for people with mobility problems and reduce the costs of unnecessary patient transfers and emergency hospital visits.

Therefore, France has been encouraging and facilitating the use of telemedicine, through different ways and in particular, by conducting a supportive strategy that aimed to guarantee confidence in telemedicine (publication of HAS recommendations, referential of available and compliant digital tools, etc.). Thus, the HAS was fully involved in the process of the development of telemedicine and it regularly published guidelines for patients⁹ and healthcare professionals¹⁰ which are didactic guides for good practises, quality and safety of telehealth acts. These guides and their summaries are real “instructions for use” as they describe for each teleconsultation, tele-expertise and telecare procedure the conditions required for a secure implementation (planning, premises, videotransmission equipment, document

⁵ [Article 24 of 2022 Social Security Financing Law Project](#)

⁶ [Amendment no 6 of 10 August 2018 of the national medical convention completed by Amendment no 8 of 30 September 2020 of the national medical convention](#)

⁷ [Decree n°2020-227 of 9 March 2020](#) repealed on 1 January 2021.

⁸ [Article 61 of the 2021 Social Security Financing Law](#)

⁹ [Comment se faire soigner à distance: Télconsultation et télésoin](#) (HAS, May 2021)

¹⁰ [Qualité et sécurité des actes de téléconsultation et de téléexpertise: Guide de bonnes pratiques](#) (HAS, May 2019) [Télconsultation et téléexpertise Mise en œuvre](#) (HAS, May 2019)

[Qualité et sécurité du télésoin: Critères d'éligibilité](#) (HAS, 3 September 2020)

[Qualité et sécurité du télésoin: Bonnes pratiques de mise en oeuvre](#) (HAS, 18 February 2021)

management, etc.). The HAS also details the conditions for the success of these procedures at each stage of the medical treatment: information and collection of the patient's consent, assessment of the relevance of using telemedicine, assessment of the patient's ability to communicate, technical means, authentication of the professional, identification of the patient, report and organisation, and continuation of the treatment.

In addition to the provision of a very clear framework, a strong reimbursement scheme was implemented in France that contributed to the development and expansion of telehealth in France (described above under question 6).

Furthermore, financial aids were made available for practitioners that are willing to equip themselves with the tools and technical solutions necessary to the telehealth practices. In particular through flat-rate annual financial aid granted by health insurance for video transmission equipment and connected medical devices¹¹, but also through programs put in place by some of the regions of France most affected by limited medical facilities which offers financial aids to make access to telemedicine easier for the towns and health professionals concerned.

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¹¹ Order of 16 August 2018 completing the amendment no 6 of the national medical convention

Germany

1. What local regulations are in place in respect of telemedicine?

There is no explicit legal framework for telemedicinal services in Germany. Rather, provisions pertaining to telemedicine can be found in various German laws.

Telemedicinal services are for example regulated in the respective State Professional Ordinances for Physicians (based on the "(Muster-)Berufsordnung-Ärzte" – MBO-Ä), the German Act on Advertising of Medicinal Products ("Heilmittelwerbeengesetz – HWG") as well as the German Social Code, Book V ("Fünftes Buch Sozialgesetzbuch" – SGB V).

2. Are healthcare professionals allowed to provide services through Telemedicine?

After being generally prohibited, in 2018 the MBO-Ä was adapted to allow exclusive telemedicinal consultations or treatments in **individual cases** if this is justifiable from a medical point of view and the required medical care is maintained, in particular by the way in which the findings are ascertained, consultation, treatment and documentation are carried out and the patient is also informed about the particularities of the exclusive of consultation and treatment exclusively via communication media.

3. What types of Telemedicine services are provided (e.g. store-and-forward; remote monitoring; real-time interactive services) and under which conditions is it possible to provide services in Telemedicine mode?

In principle, all kind of telemedicinal services can be offered in Germany. However, it must be medically justifiable, the necessary medical care must be guaranteed, and the patient must be informed about the particularities of exclusive consultation and treatment via the specific communications channel (i.e., video/chat/etc.).

The question of whether a telemedicinal treatment / consultation is suitable must be assessed by the treating physician in each individual case. Should they come to the conclusion that no adequate treatment or consultation can be provided by telemedicinal services, a regular in-person visit should be recommended instead.

4. What are the requirements for the advertising of Telemedicine services?

The advertisement for such telemedicine services is a hotly debated and litigated topic in Germany. The relevant provision, Sec. 9 HWG, basically prohibits the advertisement for telehealth services unless, according to generally accepted professional standards, personal medical contact with the person to be treated is not required. The question of which telemedicinal services can be advertised under that restriction is rather open. In October of 2021, the Federal Court of Justice heard a corresponding case, in which the presiding judge of the 1st Civil Senate pointed out that the change to Sec. 9 HWG could extend the possibilities of telemedicine and also more broadly permit such treatments. A reasoned judgement in this case is however not expected until 2022.

In these proceedings, the Court of Appeal of Munich had previously decided with regard to the advertising of telemedicine services that only such specific remote treatments may be advertised to people for whom compliance with recognised professional standards is ensured, i.e., if proper treatment and consultation using communication media is fundamentally possible according to the recognized state of medical knowledge.

5. Are there local laws regulating reimbursement for services through Telemedicine?

Video consultations performed by physicians are only reimbursable if done using a video service provider certified according to Annex 31b to the Federal Collective Agreement for Physicians (Bundesmantelvertrag-Ärzte).

In general, not all German health insurance companies offer reimbursements for telemedicinal services, which thus have to be paid by patients on their own in some cases. However, more and more German health insurance companies conclude agreements with telemedical service providers, thus ensuring such services being reimbursable.

6. Are there any incentives (also fiscal benefits) promoting telemedicine or the digitalisation of health services?

The Digital Healthcare Act (DVG), which came into force at the beginning of 2020, aims to advance the digitalisation of German healthcare. Among other things, doctors are now able to prescribe digital health apps to their patients in the same way as medicines, at the expense of health insurers. However, such digital health applications (DiGA) of this kind operate in a highly regulated area. Even at the design stage, attention must be paid not only to the basic requirements of medical product law, but also to the protection of particularly sensitive patient data. There are also special features in distribution, especially in advertising and the requirements for smooth reimbursement by health insurers.

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Italy

1. What local regulations are in place in respect of telemedicine?

Telemedicine is not expressly regulated by Italian law. However, the Italian Ministry of Health (“**MOH**”) and the Italian National Institute of Health (“**ISS**”) adopted guidelines providing principles and rules related to Telemedicine services.

Specifically:

- On March 17th, 2014, the **MOH** adopted [national guidelines on telemedicine](#)¹² (hereinafter the “**Guidelines**”). The document provides several principles and rules applicable to telemedicine;
- On April 13th, 2020, the ISS published the Interim provisions on telemedicine healthcare services during COVID-19 health emergency¹³. The document provides support for the realisation of services in telemedicine during a COVID-19 emergency, offering indications, identifying operational problems and proposing solutions supported by evidence, but also easily dispensable in practice.
- On October 10th, 2020, the ISS published interim guidance on telemedicine health services for Pediatrics during and beyond COVID-19 pandemic¹⁴. The document provides the scientific indications to support the implementation of telemedicine health services for pediatric patients, both in early childhood and in developmental age, and during the different phases of the COVID-19 pandemic.

On October 27th, 2020, the MOH issued the National Indication for the providing of telemedicine services¹⁵ (“**National Indication**”). The document provides practical indications related to the management and delivery of health services through telemedicine.

2. Are healthcare professionals allowed to provide services through Telemedicine?

Yes, in principle, healthcare professionals may provide services via telemedicine. Anyway, the provision of healthcare services by telemedicine, shall be done in accordance with the relevant health laws and regulations, ethics code, order¹⁶ and bioethics guidelines¹⁷, Guideline and National Indication (in this sense, reads answer provided under section 3 below). Healthcare professionals providing services by telemedicine are fully liable for their professional activities¹⁸.

¹² See: http://www.salute.gov.it/imgs/C_17_pubblicazioni_2129_allegato.pdf.

¹³ See: https://www.iss.it/rapporti-covid-19/-/asset_publisher/btw1J82wtYzH/content/rapporto-iss-covid-19-n.-12-2020-indicazioni-ad-interim-per-servizi-assistenziali-di-telemedicina-durante-l-emergenza-sanitaria-covid-19.-versione-del-13-aprile-2020

¹⁴ See: https://www.iss.it/rapporti-covid-19/-/asset_publisher/btw1J82wtYzH/content/rapporto-iss-covid-19-n.-60-2020-indicazioni-ad-interim-per-servizi-sanitari-di-telemedicina-in-pediatria-durante-e-oltre-la-pandemia-covid-19.-versione-del-10-ottobre-2020

¹⁵ The National Indication was approved by the permanent conference for relations between the state, the regions and the autonomous provinces of Trento and Bolzano on December 17th 2020, see: <http://www.statoregioni.it/media/3221/p-3-csr-rep-n-215-17dic2020.pdf>

¹⁶ In this sense, please note that Biologists – according to the relevant ethic code and order - could not visit patients by telemedicine. However, as consequence of Covid-19, the Order of Biologists, decree n. N. 103 dated November 5th, 2020, authorised biologists to use telemedicine in order to provide their service online “[...]provided that the professional adopts all the technical precautions necessary to ascertain the identity of the patient and their major age (and, if of minors, the consent of the parents or of the operators of parental responsibility), as well as the tools necessary to guide the patient in the detection of the measures, preferring for this purpose the use of video links”.

¹⁷ Pursuant to Section 3, p. 10, National Indication.

¹⁸ Pursuant to Section 3, p. 10, National Indication.

Moreover, it should be noted that according to the National Indication, telemedicine may be useful in case of health emergency, monitoring of those diseases significant for the NHS governance; accessibility to diagnostic services and continuity of care; monitoring of patients remotely. Telemedicine may be used also for medical certification whether: (i) the patient medical contact, albeit via video call, can be valid, truthful;(ii) the anamnestic information can be acquired directly from the applicant; (iii) the data are collected are certain and objective, immediately transmitted; (iv) the certificate can be released immediately and in a certified way.

3. *What types of Telemedicine services are provided (e.g., store-and-forward; remote monitoring; real-time interactive services) and under which conditions is it possible to provide services in Telemedicine mode?*

Telemedicine services may be provided by tele-examination¹⁹, teleconsultation²⁰, health-medical teleconsultation (or tele-cooperation²¹), tele-healthcare²², tele-reporting^{23,24}.

- **Tele-examination** is a medical act in which the doctor interacts remotely in real time with the patient, even with the support of care-giver. During the tele-examination it is possible to prescribe medicinal products and health treatments. For this purpose, it is necessary that the doctor can see and interact with the patient at a distance (through a telecommunications infrastructure). Such examination can take place in real time or it can be deferred. However, according to the National Indication, considering also the Doctors Ethic Code, tele-examination shall not be intended as the unique approach to manage the doctor/patient relation. Tele-examination, pursuant to the National Indication, shall be intended as a way to manage patients whose diagnosis has already been formulated during a physical consultation.

In this sense, tele-examination can be provided in the case of patients that do not require a physical examination (traditionally consisting of inspection, palpitation, percussion and listening) and when at least one of the following conditions are met:

- i the patient needs the service in the context of an individualised pathway/diagnostic therapeutic pathway;
- ii the patient is placed on a follow-up pathway concerning known disease;
- iii the patient suffering from a known disease needs a check or monitoring, confirmation, adjustment or change of the therapy in progress (e.g., renewal or modification of the therapeutic plan);
- iv the patient needs anamnestic evaluation for the prescription of diagnostic tests, or staging of a known or suspected pathology;
- v the patient needs the doctor to verify the results of the tests carried out, which can be followed by the prescription of any further information, or a therapy.

¹⁹ Pursuant to Section 2.3.1, paragraph 3, of the Guideline.

²⁰ Pursuant to Section 2.3.1, paragraph 4, of the Guideline.

²¹ Pursuant to Section 2.3.1, paragraph 5, of the Guideline and National Indication, page 7, section "Teleconsulenza medico-sanitaria".

²² Pursuant to National Indication, page 7, section "Teleassistenza da parte di professioni sanitarie (Infermiere/fisioterapista/ logopedista etc)"

²³ Pursuant to National Indication, page 7, section "Telerefertazione".

²⁴ Please note that, according to the National Indication, the e-triage should not be included in the telemedicine services. National Indication, p. 8, reads as follow "the triage or telephone consultation carried out by doctors or health professionals to patients in order to indicate the most appropriate diagnostic/therapeutic pathway and the need to perform the visit quickly in presence or remotely or the possibility of postponing it to a later time by assigning a new appointment, is not part of the activities ascribable to telemedicine"

- **Teleconsultation**, is a medical act in which the healthcare professional interacts remotely with one or more doctors to discuss, also via video call, the clinical situation concerning a specific patient, based primarily on the sharing of all clinical data, reports, images, audio-video.

The sharing of documents takes place electronically. Teleconsultation between healthcare professionals can also take place in an asynchronous manner. When the patient is virtually present, the teleconsultation takes place in real time and is configured as a multidisciplinary tele-examination.

The purpose of teleconsultation is to share the approaches by healthcare professionals involved in a specific case. It is also a way to provide a second specialistic opinion regarding the concerned specific case. The teleconsultation will be included in the final report.

- **Health/medical teleconsultation** is a consultation among healthcare professionals (not necessarily doctors). It is provided by two or more healthcare professionals having different responsibilities regarding a specific case. It concerns the request of support, from a healthcare professional to another healthcare professional, during the execution of health activities.
- **Tele-healthcare** concerns healthcare professional's interaction (e.g., nurses/physiotherapist etc.), where each healthcare professional provides the relevant virtual assistance to the patient. The purpose of remote assistance is to facilitate the correct performance of assistance activities, which can be carried out at home.
- **Tele-reporting** is a report issued by a doctor who has requested a clinical or instrumental examination. The tele-report is transmitted through digital and telecommunication systems, formalised with a qualified electronic or digital signature of the relevant responsible doctor.

Moreover, regarding tele-reporting the relevant national scientific body issued a guideline²⁵. According to the applicable guidelines, in case of a final report issued by a radiologist following a teleconsultation with another radiologist, the written opinion of the consultant radiologist, in order to be legally valid, shall be signed by the consultant radiologist his/herself in a legible manner via a qualified electronic or digital signature.

Please finally also note that – during the teleconsultation – the radiological medical act is guaranteed by the radiologist present at the execution of the examination. In such moment, the medical professional shall inform the patient regarding the teleconsultation, shall have the patient consent both to do so and to transmit the diagnostic image.

In order to provide Telemedicine services:

- **Patient shall be adequately informed and shall consciously accept, before telemedicine services are provided:**
 - the type of service (i.e., what the service consists of, what its objective is, what are the advantages that the patient may have and any possible risks);
 - the method used to manage and maintain the information and who will have access to the patient's personal and clinical data;
 - the facilities and professionals involved and relevant duties and responsibilities;
 - the identification and relevant details of the owner/s of the processing of personal data and of at least one person in charge (responsible person) if identified, indicating how to know the updated list of responsible people and relevant contacts;
 - the patients' rights regarding their data²⁶.
- **The following infrastructure requirements shall be guaranteed:**
 - connection infrastructure always available between doctors and patients
 - web portal accessible to doctors in order to manage their patients

²⁵ Guideline regarding the radiological medical report issued by the Italian Society of Radiology (SIRM).

²⁶ Pursuant to Section 2, p. 10, National Indication.

- web page accessible to healthcare professionals both from computer, tablet, smartphone
- easy access for patients (i.e. easy login method) with adequate identity verification and possibility to connect with the digital tools common available (i.e. computer, tablet, smartphone)
- compliance with the GDPR for the processing of personal data
- certification of the relevant hardware and/or software, as a medical device where required, adequate for the type of telemedicine service to be performed²⁷.

- **Telemedicine services report.**

- At the end of the tele-examination or other telemedicine services, the doctor or other health care professional – where applicable by reason of the service provided – shall conclude with a report indicating also (i) the presence of any assistant, caregiver or other healthcare provider; (ii) the quality of connection infrastructure and the adequacy of it in accordance with the service provided; (iii) valid digital signature.
- The report, in compliance with the privacy and cyber security laws and regulations, shall be available to the patient by his/her preferred technology solution and shared with other healthcare professional if requested by the patient.

4. What are the requirements for the advertising of Telemedicine services?

There are no specific laws regulating the advertising of telemedicine services.

It derives that rules normally applicable to the promotion of subjects/companies providing healthcare services shall apply also to telemedicine. To be more specific, according to the provisions contained under Law Decree n. 223/2006 (converted in Law n.

248/2006, the so called “Legge Bersani”), both professionals and companies providing healthcare services can promote their activity online and offline, provided such promotion complies with the following principles:

1) According to what is provided under Law n. 145/2018 (so called “Budget Law 2019”), the advertising shall have an informative purpose (meaning should not have promotional and/or suggestive purposes) and can contain the only following information (see Article 2 of Law Decree n. 223/2006):

- (i) title and professional specialisations;
- (ii) characteristics of the services offered;
- (iii) fees and total costs of the services in accordance with transparency and truthfulness criteria.

In addition to that, the promotional message shall respect “[.] *the patient’s free and conscious determination, to protect public health, the dignity of the person and his right to correct health information*”.

2) According to the provisions contained under both the legislative decree n. 206/2005 (so called “Consumer Code”, see, in particular, Article 21 thereof) and the relevant ethical code, they should not provide misleading and/or untrue information (otherwise the relevant conduct may be regarded as a misleading commercial practice), and/or information that is incorrect and/or violates professional secrets and/or that may be ambiguous or denigratory.

²⁷ Pursuant to Section “Prestazioni sanitaria a distanza: elementi e standard necessari”, p. 12, National Indication.

5. Are there local laws regulating reimbursement for services through Telemedicine?

Yes, according to the Guidelines and National Indication services provided in telemedicine can be reimbursed by the NHS.

In order to do so, specifically pursuant to section 3.2 of the Guideline, the following aspects shall be considered:

(i) organisational model

Telemedicine organisation model should be: Users/Provider/ Services Centre ("**Telemedicine Business Model**").

In the Telemedicine Business Model,

- the User, is the individuals using a telemedicine service, and for this purpose sending health information and/or receiving relevant results. User can be: the patient / caregiver (tele-examination; teleconsultation); the doctor in the absence of the patient (teleconsultation); the doctor or another health care professional (tele-examination, tele-cooperation).
- the Provider, is who provides healthcare services through a telecommunications network (or infrastructure). A Provider may be:
 - Entities belonging to the Italian National Healthcare System (NHS) [9], authorised or accredited, either public or private;
 - Healthcare professionals belonging to the NHS (i.e., general practitioners, paediatricians, medical specialists). The Provider receives health information from the User and returns the results of the service.
- the Service Centre has the responsibility for the management and maintenance of the information system, including transmission and storage of relevant information. Please note that Provider can also act as Service Centre.

(ii) relevant authorisations

Specifically, Providers should hold: (i) all authorisations normally required for the performance of health and socio-health activities in a traditional manner (see Article 8-ter of Italian Legislative Decree n. 502/92); (ii) regional accreditation where the Provider facility is based (see Article 8-quarter of Italian Legislative Decree n. 502/92) and in case telemedicine services intended to be reimbursed by the NHS, the Provider should also conclude contractual arrangements with the relevant regions (see Article 8-quinques of Italian Legislative Decree n. 502/92); (iii) any other additional authorisations which may be required in relation to the IT tools to be used for the provision of the concerned healthcare services.

(iii) By contrast to companies, an individual doctor providing health services by using telemedicine does not need of any prior authorisation being the registration of doctor before the relevant professional order sufficient in order to provide healthcare services in telemedicine). In the case that a doctor is also interested to have such services reimbursed by the NHS, they should conclude an agreement with the NHS that covers the ethical aspects, processing of personal data with electronic tools, professional responsibility²⁸.

- Ethical aspects: ensuring that the doctor-patient relationship can be developed and improved also through telemedicine (by way of example, dedicating the necessary time in order to adequately inform the patient, beyond the informed consent);

²⁸ Pursuant to Section 8 of the Guideline

- Processing of personal data: personal and health data necessary for the provision of telemedicine services falls within the processing of sensitive data carried out by electronic means. Such data shall be processed pursuant to Italian Legislative Decree 196/2003 and subsequent amendments and additions.
- Professional responsibility: for this purpose may be also significant an adequate information on treatments, informed consent of patients, rights of the client over their personal data.

Moreover, for all the services provided in telemedicine, will be applied the remuneration/professional fee system already in force for the provision of the same services in presence²⁹.

6. Are there any incentives (also fiscal benefits) promoting telemedicine or the digitalisation of health services?

There are several national incentives that may be applicable. By way of example, among others,

- The Italia National Recovery and Resilience plan (“PNRR”) – approved by the European Commission the 22nd of June 2021 - provides as goals innovation, digitalisation and health.

Regarding the health sector, the PNRR provides as goals: (i) proximity networks, structures and telemedicine for territorial health care (ii) innovation, research and digitalisation of the national health service. Specifically, in the light of the issues emerged during the health emergency, telemedicine appears as a way to overcome the fragmentation and lack of healthcare services homogeneity provided in the whole national territory and to support patient homecare. 40% of the Italian population is affected by chronic diseases. Telemedicine may be a way to manage and support the patients directly from home.

The PNRR has a duration of six years, from 2021 to 2026, and a total size of 672.5 billion euros (of which 312.5 grants).

- According to Law n. 178/2020 (“Budget Law”), regions allocate 0.5 % of EUR32 million in order to incentivise purchase - by public and private health facilities accredited with the NHS - of devices and IT applications that enable remote reporting, consultation between specialists and remote home assistance³⁰.

Innovative start-up regime may be applied.

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²⁹ National Indication, p. 9.

³⁰ In this sense reads paragraphs 444 and 442, article 1, Budget Law 2021.

The Netherlands

1. What local regulations are in place in respect of telemedicine?

In the Netherlands there is no explicit legal framework for the use of telemedicine. However, there are various laws and regulations that are relevant to the use of telemedicine. For example, the Dutch legislative framework on medical devices (the Medical Device Act, Medical Devices Regulations and Medical Devices Decree), legislation regarding data protection (GDPR) and the Dutch Medicines Act. Also, the Dutch Individual Health Care Professionals Act specifies reserved actions that only certain groups of medical professionals may perform.

Other relevant regulations:

- The Healthcare Quality, Complaints and Disputes Act. This act describes standards for the provision of good quality care. The care provider must meet these standards for every healthcare request and situation.
- The Medical Treatment Contracts Act. This act provides rules about the treatment contract between the physician and the patient (including the establishment and termination of the contract, informed consent, confidentiality, rights of minors and proper provision of care).
- The Dutch Processing of Personal Data in Healthcare (Additional Provisions) Act. This act contains safeguards for clients in electronic data interchange.

2. Are healthcare professionals allowed to provide services through Telemedicine?

Yes, healthcare professionals may provide services via telemedicine, provided they meet the conditions.

The Royal Dutch Medical Association (KNMG) has published various guidelines that are relevant to telemedicine, e.g., the KNMG Guideline 'Dealing with medical data'. This guideline also includes some provisions from the former KNMG guideline 'Online physician-patient contact'³¹. According to this guideline, a physician may only decide to have online contact with a patient without an existing relationship if the quality of care is sufficiently guaranteed, the risk of adverse effects is sufficiently limited and if the care provided is of benefit to the patient. The responsibility for the decision to maintain online contact with the patient and the responsibility for the medical treatment lies with the physician. The physician can be held accountable for this.³² This guideline provides terms and conditions for online consultation with medical advice:

- The physician has sufficiently informed the patient about the procedure for online contact;
- The physician must ensure that the services they provide online (such as patient consultations and examinations via video conferencing) take place outside the observation of others;
- The physician has sufficient relevant and reliable data from the patient to be able to give a medically sound individual advice;
- The physician adheres to the rules that apply in their field of expertise for the quality and safety of care and the rights of the patient;
- The physician has sufficiently established the identity of the patient;

³¹ Herzien: KNMG-richtlijn Omgaan met medische gegevens | KNMG.

³² KNMG Guideline for dealing with medical data 2021, p. 53.

- The physician clearly indicates that their advice is based on the information provided by the patient and any available records;
- If the physician is not the patient's (general) practitioner, they will inform the patient's own general practitioner about the advice they have given to the patient.³³

The prescription of medicines is subject to the Dutch Medicines Act. The prescription of medicines following online contact between the prescriber and the patient is subject to rules and conditions. Pursuant to article 67 Medicines Act, it is prohibited to prescribe medicines via the internet to persons whom the prescriber has never met in person, or whom the prescriber does not know, or whose medication history the prescriber does not have at his disposal. This does not include communication via the internet between a physician and a patient based on an existing physician-patient relationship. According to parliamentary papers, the internet must be regarded as an addition to the existing means of communication and can have a clear added value.³⁴

The KNMG Guideline 'Dealing with medical data' stipulates the following conditions for prescribing medication pursuant to article 67 Medicines act in addition to the conditions already stated for online consultations with medical advice:

- The prescribing physician must have met the patient;
- The prescribing physician must know the patient;
- The prescribing physician must have the patient's medication history;
- There is sufficient reliable and relevant information available to exclude any contraindications to the intended medication and to decide to prescribe the medication on that basis;
- Based on the available information and in view of the medication to be used, there is no reason to perform a (supplementary) physical or other examination;
- The physician sufficiently informs the patient about the use of the prescribed medication and any possible side-effects thereof.³⁵

For the duration of the COVID-19 crisis, the Dutch inspectorate for Health and Youth care permitted physicians to prescribe medication online. As of 1 June 2022, this temporary exception to article 67 Medicines Act has been reversed. Therefore, it is in principle no longer allowed for a physician to prescribe medication following a video consultation if a patient has not previously been seen physically by the prescriber. During the COVID-19 crisis this was possible if the prescriber was able to see the patient's current medication history (including allergies) and the prescriber informed the patient's primary care provider and/or GP as soon as possible afterwards.³⁶

However, healthcare professionals have indicated that they are experiencing problems now that this arrangement is ending. Consequently, the Royal Dutch Medical Association started an evaluation of the possibility and desirability of online prescription, on the basis of which it will restart discussions with the Ministry of Health, Welfare and Sport and the Dutch inspectorate for Health and Youth. The Royal Dutch Medical Association expects to be able to provide more information in early 2023.

In the meantime, the Dutch inspectorate for Health and Youth has indicated it will take the developments in healthcare practice into account in their supervision. If it comes across online prescribing, they will assess two factors:

- i). does the method used prioritise patient safety, and
- ii). have healthcare practitioners acted in a careful and accountable manner?

³³ KNMG Guideline for dealing with medical data 2021, p. 54-55.

³⁴ *Kamerstukken II 2005/06, 29359, nr. 81.*

³⁵ KNMG Guideline for dealing with medical data 2021, p. 55-56.

³⁶ Regeling Online medicijnen voorschrijven na videoconsult vervalft per 1 juni | KNMG.

3. What types of Telemedicine services are provided (e.g., store-and-forward; remote monitoring; real-time interactive services) and under which conditions is it possible to provide services in Telemedicine mode?

In principle, healthcare can be offered in any form, as long as the above-mentioned regulatory framework is met. Various forms of telemedicine can thus be offered, using different communication channels. Some (additional) conditions may apply to different communication channels.

With the emergence of the COVID-19 pandemic, the use of video conferencing has increased. The KNMG Guideline 'Dealing with medical data' gives some advice on the use of video conferencing. It indicates that it is always preferable to use the most secure and certified application, for example one that has been specially developed for healthcare. If the physician is not sure whether the application they want to use is sufficiently secure, they must inform the patient in advance that the communication may not be sufficiently secure and the patient should give their consent to its use. However, in the Guideline it is explicitly stipulated that the patient's consent is not a licence for not complying with security obligations. The legal requirements and standards for the exchange of privacy-sensitive healthcare information must always be complied with. It is also advised in the Guideline to delete chat history after each conversation.³⁷

4. What are the requirements for the advertising of Telemedicine services?

In the Netherlands, there are no specific laws regulating the advertising of telemedicine services. However, article 6:194 Dutch Civil Code prohibits misleading advertising in general. Some selfregulatory codes also apply, such as the Dutch Advertising Code. The Dutch Advertising Code contains rules which all advertising must comply with and stipulates that advertising may not be misleading or contrary to the truth. The Dutch Advertising Code also contains some more subjective standards, for example that advertising may not be gratuitously offensive or contrary to good taste and decency.

As a part of the Dutch Advertising Code, there is also a special advertising code for medical devices and a special advertising code for medical self-care devices.

However, advertising for telemedicine services cannot include advertising for prescription medicines, as this is generally forbidden under Dutch law.

5. Are there local laws regulating reimbursement for services through Telemedicine?

The Dutch Healthcare Authority (NZA) has published a digital care costing guide (*Wegwijzer bekostiging digitale zorg 2022*). This guide is not specifically about telemedicine but focuses on digital care in general, including 'e-care' such as e-diagnosis, e-consultations, monitoring and e-prevention intervention in the event of an individual of high risk.

In the guide it is explained that digital care can only be reimbursed if it meets the so-called package criteria as follows from the Dutch Healthcare Insurance Act and the Dutch Long-Term Care Act. The most important criteria are that the treatment must be safe and proven effective. The Dutch Healthcare Insurance Act describes which medical aids (such as eHealth technology) qualify for reimbursement from the basic health insurance package.³⁸

³⁷ KNMG Guideline for dealing with medical data 2021, p. 52.

³⁸ Wegwijzer bekostiging digitale zorg 2022, p. 8.

Based on the guide, the general rule is that if existing, already insured care is offered in an eHealth form, that care remains insured care if the composition and effectiveness does not essentially change from the original care.³⁹

Also, the Association of Dutch Health Insurers and the Dutch patients' federation have recently taken the stand promoting telemedicine and advocating a right to digital healthcare. They want patients to have a choice between going to see a physician at the hospital or receiving digital healthcare at home.

6. Are there any incentives (also fiscal benefits) promoting telemedicine or the digitalisation of health services?

In the Netherlands, several important initiatives are launched by the government to facilitate and strengthen eHealth.

In 2021, the Dutch Healthcare Authority (NZA) increased funding for e-Health. This means that the costs of telehealth – for example an online consultation by video conferencing – can be reimbursed in the same way as face-to-face healthcare services provided by a general practitioner (GP) or a medical specialist. By making the regulations more flexible, the government is making it easier for GPs to assess a patient's situation. In addition, speech therapists and medical specialists now have more opportunities to provide therapy and care online.⁴⁰

There are also some financial incentives from the government that encourage teledermatology. From 2020, the assessment of dermatological conditions at the request of a GP will be subject to a free rate instead of maximum rates, giving healthcare professionals and healthcare insurers room to make agreements on digital care and removing potential barriers to scaling up teledermatology in primary care.⁴¹

The Dutch government is investing in a digital personal health environment, where people can access their health data online in one place to make people more involved in their own health. Personal health environments are currently free for users and are paid for by the government.⁴²

In April 2021 the Dutch government accepted a legislative proposal from the Dutch minister of Medical Care regarding a law concerning mandatory electronic exchange of medical information between healthcare providers. The aim of this act is to ensure that all medical data of all healthcare providers is stored electronically and accessible, and no longer written or via fax. This to promote efficiency and to avoid mistakes. The legislative proposal will now be assessed by the Dutch House of Representatives.

The Dutch government also aims for more awareness of 'smart healthcare solutions'. For this purpose, the Dutch government has set up the website Zorg van Nu. On this website, the government focusses on the innovation within the eHealth sector and promoting smart eHealth solutions. In addition to the annual Dutch eHealth week, the eHealth Rally was introduced, to draw more attention to innovation and smart healthcare solutions.

Other initiatives:

- The Ministry of Health, Welfare and Sport (VWS) has set up a range of special programmes to speed up patient-professional information exchange in various sectors (VIPP);
- The Dutch National Health Care Institute (ZIN) has formulated a plan of action to stimulate the use of digital care in practice.

³⁹ Wegwijzer bekostiging digitale zorg 2022, p. 8.

⁴⁰ Stimuleren gebruik e-health | E-health (digitale zorg) | Rijksoverheid.nl.

⁴¹ Wegwijzer bekostiging digitale zorg 2021, p. 15.

⁴² [Waar kan ik een persoonlijke gezondheidsomgeving \(PGO\) voor gebruiken? | Rijksoverheid.nl](#)

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Poland

1. What local regulations are in place in respect of telemedicine?

There are several acts which set out admissibility criteria and/or organisational standards for telemedicine:

1. The Act of 15 April 11 on medical activity which stipulates that health care services may be provided through IT systems or communication systems.
2. The Act of 27 August 2004 on health care services financed from public funds (as amended) which, as of January 2015, allows, without the need to conduct a personal examination of a patient, the issuing of:
 - a prescription for the continuation of treatment and/or
 - orders for the supply of medical devices as a continuation of the supply of medical devices, if it is justified by the patient's health condition that is reflected in the medical records.
3. The amendment of the Act on the information system in health care and certain other acts (introduced in December 2015), which allows patients to be examined via IT systems and/or communication systems.
4. The Ordinance of the Minister of Health of 31 October 2019 amending the ordinance on guaranteed benefits in the field of primary health care, which introduced the provision of medical advice at a distance using IT systems or communication systems into the scope of financed health care services.
5. The Act of 5 December 1996 (as amended) on the professions of physician and dentist, which allows them to provide services through IT systems or communication systems.

One of the COVID-19 related regulations, i.e., the Ordinance of the Minister of Health of 12 August 2020 on the organisational standard of tele-advising in primary healthcare (as amended) effective from 15 March 2021, which sets out the circumstances in which the provision of medical advice is not allowed without a physical examination of a patient.

2. Are healthcare professionals allowed to provide services through Telemedicine?

Yes, the healthcare professionals can provide services through telemedicine.

The Ordinance of the Minister of Health of 12 August 2020 on the organisational standard of tele-advising in primary healthcare lists circumstances in which the provision of services through telemedicine is not allowed, i.e.:

- when a patient visits a GP, nurse, or midwife for the first time
- when a patient has a chronic disease, and their condition has worsened, or the symptoms changed
- when there is a suspicion of cancer
- if in other cases, the patient or their legal custodian does not consent to the services being provided remotely

- when it concerns a child under 6 years of age (although telemedicine is allowed when the services concern follow-up advice during treatment, determined as a result of a personal examination of the patient, which can be given without a physical examination).

Providing services through telemedicine is allowed in the following cases:

- for issuing a prescription for continued treatment,
- for issuing a referral for test or examination and discussing the results of such,
- for issuing sick leave.

In addition, remote contact with a doctor is required whenever there is a suspicion of coronavirus infection.

3. What types of Telemedicine services are provided (e.g., store-and-forward; remote monitoring; real-time interactive services) and under which conditions is it possible to provide services in Telemedicine mode?

There are no specific rules on the types of telemedicine services that are allowed. In general, telemedicine can be provided by GPs, nurses or midwives in the form of telephone advice, videocall, audio chat, text chat or (in exceptional cases) by email.

When giving advice virtually, the doctor may also use and supervise a diagnostic test that is performed by a patient at home with a telemedicine device constituting a medical device (e.g., blood glucose or ECG measurement).

Medical centres are obliged to provide information on the possibilities and organisational standards of the telemedicine. The information should include the following data:

- a list of services that are provided only if there is a direct visit,
- a system through which doctors provide teleservices,
- how to schedule teleservice,
- the method that the medical centre uses to establish contact with the patient to provide teleservices and the manner in which they are provided,

the possibility of a direct visit taking place when it is necessary.

In addition, there is a pilot programme concerning use of electronic stethoscopes in basic healthcare (introduced by the Ordinance of the Minister of Health dated 16 April 2021). The aim of the pilot programme is to assess the effectiveness of health care services in the field of basic healthcare with the use of electronic stethoscopes, to diagnose the respiratory system and potential health problems of patients with existing respiratory diseases after they have been infected with the SARS-COV-2 virus.

It seems therefore that new types of telemedicine could be successively introduced in Poland.

4. What are the requirements for the advertising of Telemedicine services?

Advertising of any healthcare services is restricted in Poland. In general, medical centres and doctors are only allowed to indirectly advertise their healthcare services, by providing information on their activities, sponsoring conferences etc.

Online advertising is allowed both for direct and indirect communications about provided healthcare services. For instance, it is possible to inform patients on the advantages of the telemedicine, such as convenient forms of contact, the possibility of obtaining medical services from any place, saving time, safety, 24/7 availability or short waiting times. However, advertising is only allowed if it does not contradict

other rules for practising the profession, in particular the dignity and prestige of the profession, as well as professional secrecy and reliability towards clients and other professionals. As an example, an advertisement would contradict those rules if it were too aggressive, too intense, or misled potential patients as to the therapies offered.

5. Are there local laws regulating reimbursement for services through Telemedicine?

Yes, the Ordinance of the Minister of Health of 31 October 2019 amending the ordinance on guaranteed benefits in the field of primary health care introduced medical advice provided at a distance using IT systems or communication systems into the scope of financed health care services. Financing is subject to certain conditions set out in the respective provisions of law, i.e., ordinances of the President of the National Health Fund.

6. Are there any incentives (also fiscal benefits) promoting telemedicine or the digitalisation of health services?

No.

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Spain

1. What local regulations are in place in respect of telemedicine?

In Spain, there are no specific regulations on telemedicine, with only a few mentions and recommendations on its use, such as those listed in the Spanish Code of Medical Ethics⁴³

Among the few mentions of telemedicine made by the Spanish regulation is Article 4.7 of Act 44/2003, 21 November, on the Organisation of Health Professions, which establishes that “*the health professions shall be practised with full technical and scientific autonomy, with no limitations other than those established by law and by the other principles and values contained in the legal and ethical code*”. In other words, doctors may opt for telemedicine if they consider it technically and scientifically appropriate, but always in due compliance with the principles and limitations contained in the Spanish Code of Medical Ethics.

2. Are healthcare professionals allowed to provide services through Telemedicine?

Yes, as long as the provision of these services is justified on public health grounds, in the interest of the patient (for example, when the patient is in a remote location where there is no access to medical services) or for reasons of health emergency (as is the case in the current situation caused by COVID-19⁴⁴).

Please note that, under the Spanish Code of Medical Ethics, it is advisable that the patient is under the face-to-face control of their doctor⁴⁵, who will be the interlocutor between the tele-doctor (who will focus on telemonitoring, teleconsultation and second opinion services⁴⁶) and the final decision-maker in the care process.

3. What types of Telemedicine services are provided (e.g., store-and-forward; remote monitoring; real-time interactive services) and under which conditions is it possible to provide services in Telemedicine mode?

In Spain, there is no specific list of care services that can be provided virtually. However, in practice it is recommended that such services be limited to (i) the provision of a second opinion after the one given by a doctor physically; (ii) occasional medical reviews; (iii) the provision of advice to other professionals in making certain decisions; and (iv) telematic home monitoring of chronic diseases or pathologies (through wireless sensors, for example).⁴⁷

⁴³Article 26 of the [Spanish Medical Ethics Code](#).

⁴⁴ In this point, the Spanish Council of Medical Associations (*Consejo General de Colegios Médicos de España*) published on 10 June 2020 a [Guidance Report](#) with different considerations on the appropriateness of the application of telemedicine in the situation originated by COVID 19. In any case, this Report stresses the complementary nature of telemedicine to face-to-face doctor-patient care and sets out the importance of respect the principles listed in the Spanish Medical Ethics Code, the defence of patient rights and patient safety as well as the respect for the health professionals. Finally, this Report also establishes that the use of telematic means is in accordance with Spanish Code of Medical Ethics provided that there is an express consent of the patient, which shall be recorded in the clinical history.

⁴⁵ It is important to mention that the Global Medical Association (AMM) - of which Spain is associate - published the [Declaration on the Ethics of Telemedicine](#), which setting out a series of principles and recommendations on telemedicine. In the absence of a unified European or national legal framework, this is one of the indicative reference frameworks available for the purpose of listing the principles applicable to telemedicine.

⁴⁶ MONTEAGUDO, L. SERRANO, C. HERNÁNDEZ SALVADOR, La telemedicina: ¿ciencia o ficción?, *Anales Sis San Navarra* vol.28 no.3 Pamplona sep./dic. 2005

⁴⁷ Article 26 of Spanish Code of Medical Ethics.

In any case, it is necessary that, for the provision of such services, the health professional's mutual/insurance company is identified, and the patient's privacy is ensured (Article 26 of the Spanish Code of Medical Ethics).

In addition, it should be noted that it is not allowed to prescribe medicines virtually without having previously carried out a clinical examination of the patient physically, as well as granting a diagnosis, except for certain specialities such as dermatology or ophthalmology or the monitoring of chronic or monitored pathologies.⁴⁸

4. What are the requirements for the advertising of Telemedicine services?

In Spain, only healthcare centres and establishments authorised to provide healthcare services are authorised to advertise these healthcare services (Royal Decree 1277/2003, of 10 October, which establishes the general bases for the authorisation of healthcare centres, services and establishments⁴⁹).

In addition, prior to advertising these services, these centres and establishments shall obtain prior authorisation from the competent health body of the Autonomous Community where their registered office is located.

5. Are there local laws regulating reimbursement for services through Telemedicine?

No, there is no regulation providing for reimbursement of services provided through telemedicine.

6. Are there any incentives (also fiscal benefits) promoting telemedicine or the digitalisation of health services?

No, currently, no incentives (economic or fiscal) are provided to promote telemedicine in Spain.

Key contacts in Spain



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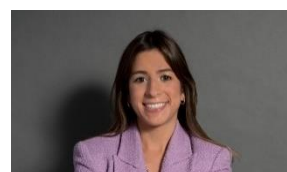
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⁴⁸ [Report on telemedicine](#) issued by Fundación 2000 on September 2012.

⁴⁹ Article 6 of [Royal Decree 1277/2003, of 10 October, which establishes the general bases for the authorisation of healthcare centres, services and establishments](#).

United Kingdom

1. What local regulations are in place in respect of telemedicine?

There are no specific laws which regulate telemedicine in the UK. Rather, telemedicine is regulated through binding standards, codes of conduct and guidelines issued by regulatory authorities. Regulation of health care services, including telemedicine, occurs at two distinct levels—health care providers and individual health care professionals.

The Care Quality Commission (**CQC**) licenses and regulates health care providers under the *Health and Social Care Act 2008* in England, including hospitals, dental practices, GP practices and aged care facilities. Equivalent bodies regulate health care providers in each of the devolved nations of the UK (the Care Inspectorate in Scotland, the Care Inspectorate Wales in Wales, and the Regulation and Quality Improvement Authority in Northern Ireland). For present purposes, we focus on the position in England.

The CQC assesses health care providers to ensure the minimum standard of care set out in the *Health and Social Care Act 2008 (Regulated Activities) Regulations 2014* is met and conducts periodic inspections to ensure compliance. In March 2017 the CQC published “*Clarification of regulatory methodology: PMS digital healthcare providers*” to clarify the regulatory requirements for telemedicine providers. The CQC states that it regulates telemedicine providers according to the same assessment framework applied to conventional health care providers, by focusing on whether the services offered are safe, effective, caring, responsive to people’s needs and well-

led. In 2019 many of the regulatory authorities and several bodies representing health care professionals agreed a set of *High level principles for good practice in remote consultations and prescribing (High Level Principles)*. Although these principles do not amount to clinical or regulatory guidance, they outline an overarching approach to telemedicine and direct health care professionals to specific regulatory guidance from regulatory authorities, where available. The High Level Principles stress the need for health care professionals to be aware of the limitations of telehealth, particularly in relation to remote prescribing and notes that UK based health care professionals offering services overseas must be aware of local regulatory requirements and comply with them in addition to UK requirements.

All providers of regulated health care services in England must register with the CQC. Before granting registration, the CQC must be satisfied the services offered by the provider meet the requirements of the *Health and Social Care Act 2008*. The CQC also undertakes enforcement action including inspection of health care provider sites in order to ensure ongoing compliance with the registration requirements.

In addition to the CQC registration, individual health care professionals are regulated by regulatory authorities (**Councils**) for each of 10 practice areas. These Councils are responsible for setting registration requirements, practice standards and codes of conduct for health care professionals in each practice area, as well investigating complaints and taking enforcement action.

2. Are healthcare professionals allowed to provide services through Telemedicine?

Yes. There are very few restrictions on the types of telemedicine services permitted in the UK. Health care professionals may offer any service within their scope of practice, provided they comply with the registration requirements for their practice area, any specific telemedicine guidance issued by the regulatory authority and operate through a service provider registered with the CQC.

Pharmacy services are a notable exception and are subject to a number of restrictions when providing online or delivery pharmacy services. From July 2015 until January 2021 all pharmacies in the

UK offering medicines online were required to apply to the UK Medicine and Healthcare products Regulatory Agency (**MHRA**) for registration as a distance selling pharmacy. Once registered, the pharmacy must display the EU Distance Selling Logo on all parts of the website where medicines are offered for sale. From 1 January 2021 this requirement was removed (except in Northern Ireland); however, the MHRA is considering introducing an equivalent UK Distance Selling Logo in future.

Under the UK *Human Medicines Regulations 2012* pharmacy and prescription only medicines may only be sold or supplied at the premises of a registered pharmacy and under the direct supervision of a pharmacist. As a result, where a delivery service is offered, the General Pharmaceutical Council states the handover of the product to the delivery agent must occur at registered pharmacy premises under the supervision of a pharmacist.

3. What types of Telemedicine services are provided (e.g., store-and-forward; remote monitoring; real-time interactive services) and under which conditions is it possible to provide services in Telemedicine mode?

There are no specific restrictions on the type of platform that may be used to provide telemedicine services, provided that health care professionals: offer services within their scope of practice; comply with the registration requirements for their practice area and any specific telemedicine guidance issued by the regulatory authority; and operate as or through a service provider registered with the CQC.

4. What are the requirements for the advertising of Telemedicine services?

There are no specific requirements for the advertising of telemedicine services *per se* in the UK and such advertising will be subject to general advertising regulations and guidance.

5. Are there local laws regulating reimbursement for services through Telemedicine?

There are no specific rules regarding the funding or reimbursement of telemedicine services. A wide range of telemedicine services are fully government funded and offered at no cost to patients by the NHS, supported by dedicated IT infrastructure provided by NHS Digital. These include GP, pharmaceutical, psychology and some dental services. Additional privately funded services are offered by a range of commercial providers.

6. Are there any incentives (also fiscal benefits) promoting telemedicine or the digitalisation of health services?

While telemedicine is already prominent in the UK health care sector, there is currently a significant drive in the UK to further promote and innovate telemedicine and digital health generally. The UK government has expressed its intention to drive innovation, including “*embracing telemedicine like never before*”.⁵⁰

⁵⁰ <https://www.gov.uk/government/speeches/building-the-best-health-system-in-the-world>.

Telemedicine, smartphone apps and wearable sensors are all examples of technologies likely to be routinely used in the

healthcare sector in the years to come. Progress towards this has accelerated during the COVID-19 pandemic, with 99% of England's GP practices now activating remote consultation platforms.⁵¹

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⁵¹ <https://www.gov.uk/government/publications/trend-deck-2021-technology>.

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