Inteligencia artificial y digitalización de la salud

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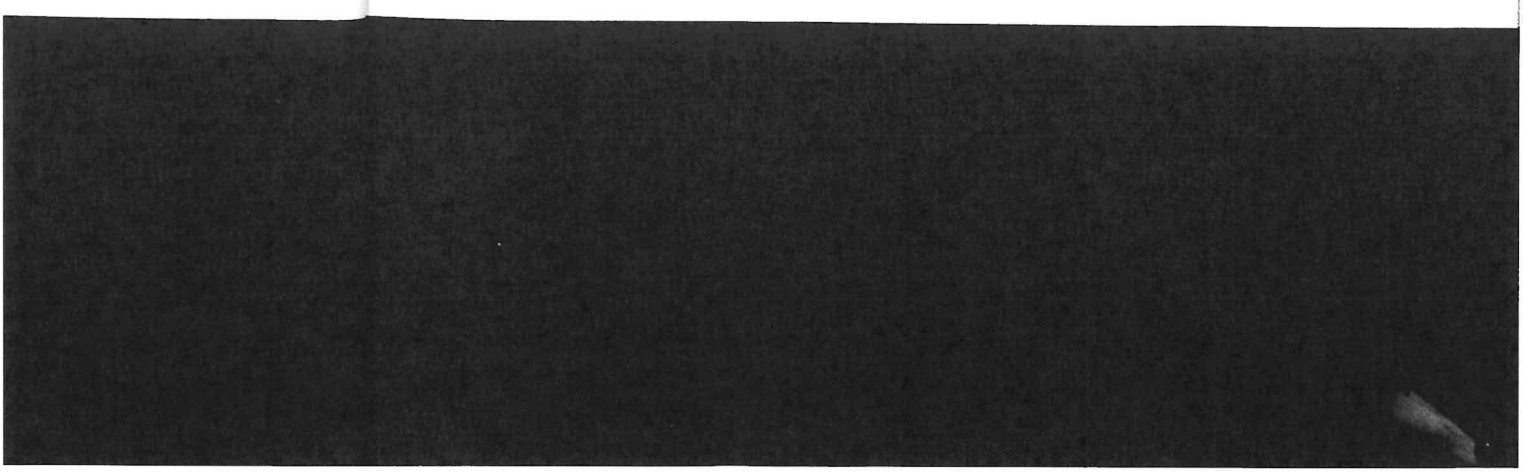

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ACCESS TO TELEMEDICINE SERVICES IN THE ITALIAN LEGAL SYSTEM

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SUMARIO

1. TELEMEDICINE WITHIN THE AXIOLOGICAL HORIZON OF THE DOCTOR-PATIENT CARE AND *TRUST* RELATIONSHIP

In outlining the regulatory framework for telemedicine healthcare activities, bringing together in dialogic discourse both domestic and European sources, I would like to focus particularly on the right of access to these services. Specifically, since telemedicine healthcare practices are characterized by a functional profile of both personal and social nature —the former consisting of patient *care*, and the latter in the *generation of data* that feeds the national/European health data ecosystem— it is necessary to clarify the extent to which access is legally protected and who are those responsible for ensuring it within the context of the care relationship.

The issue first requires focusing on the axiological horizon of telemedicine and on the normative framework within which the patient's right of access takes shape. In the Italian context, the reference value system is that well-established by Law n. 219/2017, which, in addition to establishing the principle of *free and informed* consent as the foundation of every healthcare treatment, promotes and enhances the *care and trust* relationship between doctor and patient, where «the patient's decision-making autonomy meets the competence, professional autonomy, and responsibility of the doctor» (Article 1).

It is precisely within the fiduciary dynamics of this relationship, where consent must be supported by personalized information, that the issue of access to telemedicine arises. This issue is not limited to the freedom of self-determination, as it occurs in a care relationship where the patient and doctor are face-to-face, but it first and foremost requires the implementation of the conditions necessary for such freedom to operate.

As is well known, healthcare services in telemedicine are provided through IT technologies when the patient and the healthcare provider are not in the same location. In the care relationship, in these cases, the technological tool acts as a *medium* for the healthcare service between the patient and the healthcare provider. This medium can either be a simple tool for visiting the

patient (televisit) or a tool for remote monitoring or control of the patient's health *status*, which can have a significant impact on the individual. Hence, the distinction of activities outlined in the 2020 State-Regions Agreement (State-Regions Conference Agreement «National Guidelines for the Provision of Telemedicine Services»), between *i) telemedicine services*, including televisit, teleconsultation, and telecare, and *ii) operational modes* of telemedicine, which include telemonitoring and telecontrol.

The Guidelines for telemedicine services, as outlined in the Ministry of Health Decree of September 21, 2022, are aimed at enhancing the care and *trust* relationship between the patient and the doctor, clearly indicating that the tools used can only serve to ensure the *continuity* of that relationship for monitoring purposes. With specific regard to the televisit, «in which the professional interacts remotely, in real time, with the patient, even with the support of a caregiver» it is stated that it cannot exhaust the mode of conducting the care relationship, as it is prohibited its use as a mode of first visit, except in exceptional cases. In essence, the televisit is limited to *monitoring activities* after the initial diagnosis has been made by the doctor following an in-person visit. This also aligns with the provisions of the Code of Medical Ethics, which expressly prohibits a doctor using information systems from replacing «the medical visit, which consists of direct interaction with the patient, with an *exclusively* virtual relationship». Therefore, the televisit can only complement the in-person visit; conversely, the use of telemedicine tools is always allowed for «activities involving the detection and remote monitoring of biological parameters and clinical surveillance» (Article 6).

In summary, the use of technology in the remote management of the care relationship must always preserve the *personal relationship* between the patient and the doctor, in which the meeting between the autonomy of the former and the competence and responsibility of the latter, aimed at safeguarding the best interest of the patient, takes place. This is precisely the axiological principle under which the opportunities and risks involved in the use of telemedicine should be balanced. On the other hand, this principle, which oversees the care relationship and prevents the technological component from replacing the interpersonal one, is an application of the fiduciary principle that governs the execution of professional services, from which the rule arises that the professional «must personally carry out the task entrusted» (Article 2232 of the Civil Code); a rule also present in the BGB (German Civil Code) and explicitly referenced in the regulation of the care relationship (see Articles 613 and 630b BGB).

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2. THE ELIGIBILITY ASSESSMENT AND THE PRECONDITIONS FOR ACCESSING TELEMEDICINE SERVICES

In the context of this framework that outlines the essential structure of the care relationship, the issue of access to telemedicine tools must be addressed. Firstly, it is essential to focus on the opportunities and risks for the user, especially when these tools are equipped with Artificial Intelligence ("AI") systems.

In light of the significant opportunities these tools offer in terms of access to healthcare services, particularly for individuals in physically and/or geographically disadvantaged conditions —opportunities promoted by Mission 6, Component 1, of the National Recovery and Resilience Plan (PNRR)— the risks to the fundamental rights of the individual can be equally considerable. At stake is the right to health, which, on the one hand, can be made effective (even only) by the use of such tools, but on the other hand, can be seriously compromised by them.

It is for this reason that access to telemedicine tools must be decided by the doctor, following the "profiling" of the patient's condition. More specifically, it is the doctor's responsibility to assess the patient's ability to use the technology correctly and safely, and to inform them about the functioning and purposes of their use. It follows that the use of telemedicine tools in the care relationship further complexifies the regulatory framework of the doctor-patient relationship, imposing additional *preventive, informational,* and, as will be explained further, *training* obligations on the doctor regarding the technology to be used and its implications on fundamental rights, with increasing intensity as the impact on the individual grows (especially in cases of telemonitoring and telecontrol). In the event that the device is equipped with AI systems, to these obligations are added those of transparency and control that Regulation (EU) 2024/1689 imposes on the deployer.

More specifically, the Ministry of Health's Guidelines on telemedicine set as a minimum requirement for patient access to these tools the passing of an *eligibility and enrollment* assessment. Namely, the prerequisite for accessing services implemented at the regional level is that the patient must be «eligible from a clinical, technological, cultural, and autonomy standpoint, or have the availability of a caregiver, if necessary, to make use of telemedicine services». It is also added that «since telemedicine is a remote service, certain technological capabilities and equipment, as well as compatible

clinical conditions for the service, are necessary, so it is important to assess whether the patient is "enrollable" for this type of service».

In this preventive obligation of the doctor, aimed at either granting or denying access, lies the problematic aspect and the novel factor compared to healthcare services provided without the use of digital devices.

In the assessment of a patient's eligibility to access the service, both internal factors (such as culture, autonomy, and clinical conditions) and external factors (such as technological equipment, digital infrastructure, and the availability of a caregiver) come into play. Both sets of factors may, in some cases, only be overcome by the patient with the help of external support provided by specific social policies. The point, then, is that eligibility to benefit from these services does not depend solely on the patient's internal, insurmountable personal conditions, but often on the lack of devices, support, and infrastructure that prevent them from accessing the services. For instance, consider a person living in a remote village with few inhabitants, who, despite being able to access teleconsultation services, cannot access telemonitoring or telecontrol services because they lack the devices capable of supporting the necessary *software*, or a caregiver to address their cultural and technological skill gaps, or the network infrastructure that would allow uninterrupted internet connection (e.g., fiber optics).

Indeed, it is precisely based on these variables that the Guidelines entrust the doctor with the *unquestionable judgment* on the patient's clinical eligibility, in order to determine whether to offer them telemedicine services. This judgment must be made by the doctor, who needs to assess not only the suitability of the tool for the patient's health condition, but also the adequacy of their technological setup and their ability to independently use the relevant devices. In practice, the doctor will need to evaluate «the aspects related to the digital literacy of the patient and/or the caregiver in order to assess the appropriateness of the devices and the degree of autonomy in their use». To this end, a visit to the patient's home may be necessary, also to assess the hygienic conditions of the living space.

In short, access to telemedicine services is conditioned by the doctor's prior and unquestionable judgment, made following the evaluation of the personal, cultural, environmental, and technological conditions of the patient and/or their caregivers as they present at the time the assessment is conducted. If the judgment is negative, the doctor excludes the patient from all or some services, without even offering the possibility to resort to them.

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Thus, the realization of the patient's interest in accessing telemedicine services is entrusted to the doctor's judgment, who must decide following the "profiling" of the patient and based on their best interest, i.e. on their right to health and, more broadly, on the principle of the free and full development of their personality. Such a judgment, then, further strengthens the accountability of the doctor's role, to the extent that if the doctor declares the patient eligible and grants access to these services, especially to operational modalities of telemedicine (telemonitoring and telecontrol), in the absence of the aforementioned requirements, they may be held liable for any resulting damages.

3. THE ELIGIBILITY ASSESSMENT THROUGH THE PRISM OF THE PRINCIPLE OF SUBSTANTIAL EQUALITY AS STATED IN ARTICLE 3, PARAGRAPH 2, OF THE ITALIAN CONSTITUTION

Therefore, the patient's access to these services involves: *i)* a preliminary phase, entirely entrusted to the doctor's unquestionable judgment, in which the doctor evaluates eligibility to decide whether or not to offer the service; *ii)* a subsequent phase, which follows a positive outcome of the first, of informational and educational nature, aimed at obtaining the patient's informed consent for access to telemedicine services. For these services, in fact, when they involve healthcare treatments (e.g., telemonitoring and telecontrol), the general rule applies. According to this rule, the patient, after receiving complete, updated, and understandable information, including details about the «benefits and risks of diagnostic assessments» may either consent to this practice or refuse it, even after initially authorizing it, in favor of the service provided in the presence of the doctor, provided that this is objectively possible, considering the patient's personal and/or geographical conditions. In such context, the principle of necessity expressed in Article 1, paragraph 6, of Law n. 219/2017 also applies. This principle states that «in situations of emergency or urgency, not only is it permitted, but it is in fact required for the doctor to provide the necessary care to an individual who is unable to make a decision», even if the only available means is telemedicine.

A first, hasty conclusion might suggest that, on the legal level, the use of telemedicine introduces nothing new in the dynamics that govern the caregiving relationship. But, indeed, this does not seem to be the case.

The detailed procedure of the eligibility assessment, referred to earlier, clearly indicates that while in healthcare treatments to be performed

in the presence of the doctor, even with the use of digital devices, the *preliminary* evaluations and *informed consent* are strictly based on the individual condition of the patient, including their free capacity for self-determination; when the relationship takes place remotely with the use of digital technologies for the administration of healthcare treatment, those same evaluations and consent also take into account the *patient's social condition*. In these cases, in practice — and this is the point — the obstacle to accessing telemedicine services can be identified by the doctor solely in the lack of technological provisions and infrastructure that allow the use of the related devices.

This is where the problem lies, and the need arises to clarify whether the doctor's conduct in refusing to offer the patient access to telemedicine services, based solely on the absence of those "external" *(social) prerequisites* that make up the eligibility assessment, can be considered lawful or not. Given that telemedicine services, as stated in the Guidelines, are intended to «overcome the fragmentation and lack of uniformity in the healthcare services offered in the territory» and to support home care, as well as, as further clarified by the PNRR, aim to provide «better support to chronic patients,» promote deinstitutionalization, and improve the quality of proximity care; well, considering all of this, that judgment of ineligibility inevitably ends up sacrificing the fundamental right to health of the patient, thereby hindering the full and free development of their personality.

These conditions ultimately translate into obstacles, into forms of substantial inequality, which prevent the individual from fulfilling their right to health. However, given that, as established by Article 3, paragraph 2, of the Italian Constitution, «it is the duty of the Republic to remove the obstacles of an economic and social nature, which, by limiting in fact the freedom and equality of citizens, prevent the full development of the human person», then a judgment of ineligibility based solely on those conditions of inequality will be unlawful if the doctor has failed to make any reasonable attempt to activate the competent public institutions to remove these obstacles. In other words, given that in these cases access is blocked by obstacles that could and should be removed by public institutions, the doctor who only acknowledges these "obstacles" and does not attempt to prompt institutional interventions, limiting to uncritically declaring the ineligibility of the patient, cannot escape liability. If those social interventions, once solicited, although they could be implemented, are not carried out, the responsibility falls entirely at the institutional level, with no legal consequences for the doctor.

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These conclusions are further reinforced by the prejudice that these omissions would also cause to the collective dimension of health, which is constitutionally protected as well. The use of telemedicine services ensures greater and more efficient access to healthcare for the entire community; moreover, in line with the principle of interoperability, by interacting with the patient's electronic health record and thus integrating into the national ecosystem and the European Health Data Space (see Regulation (EU) 2025/327), telemedicine contributes to enhancing digital healthcare with high-quality data, offering enormous benefits for the community in terms of improving the healthcare system and disease prevention.

4. THE NECESSARY INTERVENTION OF PUBLIC INSTITUTIONS FOR THE EFFECTIVE REALIZATION OF THE RIGHT TO ACCESS TELEMEDICINE SERVICES

The promotion and realization of the right to access to telemedicine services also requires the development of a technological/informatics culture and ethics, both for healthcare operators and for users. Specifically, in order to offer healthcare services through these methods, the healthcare operators must possess both *technical and relational skills*, as they need to manage remote relationships with patients and other healthcare professionals. This thus enhances the general training obligations of doctors, considering that «the initial and continuous training of doctors and other healthcare professionals includes training on relationships and communication with patients» (Art. 1, paragraph 10, Law n. 219/2017). In addition, there are also skills related to data protection.

The legal consequence of this training aspect is found in the definition of the standard of diligence and expertise of the professional and the healthcare facility in which they operate, with clear implications for the liability judgment. Moreover, in the context of the relational dimension of care and *trust*, since the doctor is required to "profile" the patient before offering them access to telemedicine services, their diligence must be assessed not according to an abstract "protocol", valid once and for all, but in relation to the specific personal, cultural, and environmental condition of the individual patient.

The professional profile of the healthcare operator, tasked with conducting the preventive assessment (whether to propose access) and the informative and educational evaluation of the patient (how to provide access), as well

as "managing" the telemedicine service, must, therefore, be supplemented by this knowledge, which can be acquired, as indicated by the ministerial Guidelines, through specific Continuing Medical Education («ECM») programs accredited by the Ministry of Health via the National Commission for Continuing Education, but also through educational initiatives provided by the National Telemedicine Platform («PNT»).

Also, the user (the patient and/or their caregiver), as mentioned, in order to be declared eligible from a technical point of view, must possess certain skills and technological equipment. Specifically, the Guidelines require that telemedicine services include information/education tools for users that are «simple and easily accessible, such as video tutorials, infographics, paper brochures, as well as possible coaching activities both in-person and remotely, to ensure appropriate use of all the technologies provided to the patient, including medical devices». In the case where the patient uses the service from their home, it is necessary for them to have «an internet connection that guarantees stable access to digital platforms».

These formative, infrastructural, and technological prerequisites, which ultimately *condition the very fulfillment* of the right to access, once again make it clear that the effectiveness of this right is not solely entrusted to the relationship of care and *trust* between the patient and the doctor, but also involves public policies aimed at realizing those very conditions. Consequently, since the patient's personal *status* is at stake, when telemedicine services are established, public social policies aimed at providing the patients who are culturally ineligible with a caregiver and those patients who are technologically unprepared or live in areas without internet coverage with the necessary tools and infrastructure, must also be simultaneously activated.

Otherwise, the inability of an individual patient to access the service, which results in a sacrifice of their right to health, could expose the competent administration to responsibility for the resulting damages. Essentially, the remote management of the care relationship through telemedicine devices involves multiple "centers of liability", not only found in the doctor and the healthcare facility but also in the institutions responsible for removing forms of substantial inequality that prevent the free and full development of the human person. In this deontological context of promoting the right to access telemedicine services, the Guidelines also include the recommendation to ensure that each telemedicine infrastructure has one or more *service centers*, which are tasked with technical assistance and the function of providing «training on the use of medical devices to patients/caregivers». Furthermore,

«they may also be entrusted with the task of distributing medical devices to the patient's home, installing them, maintaining them, as well as retrieving and sanitizing them at the end of the service».

Given that the realization of the right to access telemedicine services does not depend solely on the patient or the doctor, as occurs in the in-person care relationship, but also requires the necessary intervention of the competent public administration, it seems reasonable to affirme that the establishment of such services should only occur when the preconditions to enable access for all people are in place, reducing the substantial inequalities that exclude some from the possibility of access. This is, in fact, a constitutional *legal prerequisite* for the service, as fundamental rights of the person (in particular, the right to health) are at stake.

Moreover, as mentioned, telemedicine tools are capable of promoting the right to health, in both individual and collective dimensions, even more intensively than what happens in the in-person care relationship; and this is especially due to the *principle of interoperability* that governs the use of the digital devices. Specifically, regional telemedicine infrastructures must be integrated with the enabling services present in the national telemedicine infrastructure («PNT»), «sharing events, data, and documents according to a common standard data model in order to ensure full semantic and syntactic interoperability» (as stated in the Guidelines). The adherence to a linguistic standard certainly allows not only to fully and accurately update the patient's health profile, making it, through the electronic health record (whose components are integrated with the regional and national telemedicine platforms), always accessible; but also to generate high-quality detailed data that can flow into the national ecosystem (EDS) and the European Health Data Space (EHDS), thus serving important collective interests.

This space facilitates individuals' access to their health data and control over them (the so-called primary use of electronic health data); at the same time, it brings benefits to society in the fields of research, innovation, policy development, prevention and response to health threats, patient safety, statistics, and regulatory activities (the so-called secondary use of health data). In short, as stated in Recital 1 of the Regulation on the European Health Data Space (Regulation (EU) n. 2025/327), it is «a key element in the creation of a strong and resilient European Health Union».

In this context, where the patient's health data are made available at any time and place, the interoperability of telemedicine with the Electronic Health

Record (FSE) established in Italy by Legislative Decree n. 179 of October 19, 2012, and implemented by the Ministry of Health's decree of September 7, 2023, assumes particular importance. The FSE is defined as «the collection of digital health and social-health data and documents generated by current and past clinical events concerning the patient, also referring to services provided outside the national health service» (Art. 12, paragraph 1).

5. TELEMEDICINE AND ARTIFICIAL INTELLIGENCE SYSTEMS WITHIN THE ANTHROPOCENTRIC FRAMEWORK OF THE AI ACT

The issues discussed so far are accentuated, even confirming and expanding the previously identified centers of responsibility, when, as is happening more and more frequently, these telemedicine devices are paired with AI systems.

When this happens, the provisions of Regulation (EU) 2024/1689 (so called, «AI Act», or «AIA»), which establishes harmonized rules on AI, certainly apply. The AI system applied to telemedicine devices falls under those qualified as «high risk systems» under the AIA; this is in accordance with the combined provisions of Article 6, paragraph 1, and Annex I, n. 11, which makes explicit reference to Regulation (EU) 2017/745 (relating to medical devices), whose Article 20 requires that medical devices conforming to the Regulation bearthe CE mark.

The extraordinary opportunities offered by the use of AI systems in healthcare are well known. When these systems are employed in telemedicine, the centers of responsibility increase, encompassing the entire value chain, especially with regard to the risk of non-compliance with the *human centric and trustworthy* principle, which, among other things, guarantees «a high level of protection of health, safety, and fundamental rights» (Recital 1).

Now, what is important to highlight for our purposes are the additional obligations, beyond those already outlined, that fall on the healthcare professional and the healthcare institution, which, within the regulatory framework of AI systems, acts as the deployer. These obligations are enshrined in Article 26AIA, and once again, within healthcare, they are not limited to the doctor-patient relationship but involve, to varying degrees, other parties, including those in the value chain (see Article 25 AIA), each of which corresponds to a separate center of responsibility.

The axiological horizon that organizes every healthcare service, regardless of the tool used, is also confirmed in the use of AI systems. In fact, the human

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centric and trustworthy dimension of AI, adopted by the EU as a prerequisite, when it infiltrates the care relationship, aligns, without contradiction, with the typical function that guides it, all aimed at promoting the patient's right to health and their *status personae*. In other words, the axiological horizon is found in the fact that, just as every healthcare treatment must serve the *best interest of the patient*, AI must also be a technology that serves «as a tool *for* people, with the ultimate aim of increasing human well-being» (Recital 6), specifically achieving the well-being of the patient, their health.

Given the high potential of AI systems in terms of opportunities, but also the risks to a person's «safety» when they are designed to be used in the care relationship as devices or accessories for telemedicine devices, it is essential to define their level of autonomy in action (specifically, of calculation) to always allow for human oversight. In the care and *trust* relationship, the doctor remains the sole person responsible for the critical evaluation and decision-making regarding the patient's clinical condition and cannot delegate this solely to the machine's strictly logical inferential processes. The AI system, after completing its complex calculations through the interactive dialogue between the patient's health data and the data sets with which it interfaces, can certainly return a diagnosis that is *objectively* more precise and up-to-date than what a single healthcare professional could provide; however, it must always be subject to the *personal* evaluation of the doctor, who is responsible for the care in the relational, *trust*-based dimension that binds them to the patient. This setup is in line with the regulations, including the ethical guidelines, governing the doctor-patient relationship of care and *trust*, and is confirmed by the draft law n. 1146/2024, containing provisions and delegation to the Government on Artificial Intelligence. This law clearly states that «artificial intelligence systems in healthcare are a support in the processes of prevention, diagnosis, treatment, and therapeutic choice. The decision is always entrusted to healthcare professionals» (Article 7, paragraph 5).

Given that in the care relationship, the interest to be protected, by all available means, is the health of the patient, AI systems for health are particularly effective tools for this purpose and, therefore, certainly to be promoted, especially in telemedicine (e.g., for telemonitoring combined with therapy administration). It is significant that the Regulation allows for practices that are generally prohibited, such as manipulative and exploitative practices, for the health treatment purposes, like, for instance, in the context of «psychological treatment of a mental disease or physical rehabilitation,

when those practices are carried out in accordance with the applicable law and medical standards» (Recital 29); similarly, the Regulation provides an exception to the general prohibition on the distribution and use of AI systems designed to identify or infer emotions when they «are placed on the market strictly for medical or safety reasons, such as systems intended for therapeutical use» (Recital 44).

In all cases where the doctor resorts to AI systems, even in delivering telemedicine services, in addition to the obligations outlined earlier, they are also subject to those arising from what is established by Article 26, paragraph 2, AIA, which stipulates that deployers (in our context, the healthcare provider) «assign human oversight to natural persons who have the necessary competence, training and authority, as well as the necessary support». Consequently, the doctor's professional profile must, first and foremost, include competence in using these systems. Specifically, the doctor must be literate in AI, meaning they must possess the necessary knowledge to make responsible choices when using such devices; and this is also facilitated through training programs promoted by healthcare institutions themselves. However, their skills are not limited to acquiring technical and IT knowledge necessary for carrying out human oversight; they must also encompass a solid ethical culture, including the seven principles for reliable AI developed in 2019 by the AI HLEG (an independent group appointed by the Commission of high-level experts on artificial intelligence) and the sixteen European principles for digital health ethics approved by the eHealth network on January 26, 2022. These principles, while not mandatory, serve as guiding criteria for the practices and various forms of self-regulation of AI systems applied to telemedicine. In line with these principles, the doctor must, in particular, ensure human oversight and control in the functioning of the employed AI system, using it strictly in the best interest of the patient, also in compliance with codes of conduct, ideally adopted (either newly or by adhering to others) by the healthcare provider. In support of this, healthcare providers are encouraged to adopt or adhere to codes of conduct (or best practices). All of these requirements are made feasible by the design requirements established by the regulations: high-risk AI systems must, in fact, be designed and developed to allow individuals to oversee their operation, ensuring their constant reliability and adherence to the anthropocentric function they are entrusted with (see Article 14AIA).

In addition, the doctor, as well as the healthcare facility they belong to, which acts as the deployer, must always monitor the robustness of the system

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and its resilience against attempts to alter its functioning, and must use it ensuring the high quality of the dataset with which the system interfaces, the full respect for the patient's privacy, and the protection of their personal data.

With these competences, when the doctor offers the patient access to telemedicine services with AI systems in order to obtain their consent, they must fulfill specific obligations of *transparency and explanation* established by Regulation (EU) 2024/1689, aimed at informing the patient that their data and its processing-whether simple or sophisticated, which may even result in a diagnosis-are being carried out through an AI system. Additionally, the doctor must explain the risks and benefits of using AI, the functioning of the related inferential process, the inputs it uses, how it generates outputs, and the role these outputs play in the decision-making process (Article 86 AIA). These explanations must be communicated to the patient in an understandable way, taking into account, as Law n. 219/2017 rightly stipulates, their specific understanding capabilities.

With specific reference to the patient's right of access to telemedicine services, the ethical principle of non-discrimination and equity in the use of AI systems, together with the principle of making digital health inclusive, assumes fundamental importance: the doctor (and the healthcare facility) must ensure equal access for all patients concerned, striving, as previously mentioned, to overcome, with all reasonable efforts, the various forms of substantial inequalities that prevent the full and free development of the human person. In doing this, a decisive role is played by the patient's *education* and the *information* that must be tailored to their specific conditions in order to achieve inclusion and allow access, even to people with disabilities or low levels of literacy. In this regard, the Italian draft law on artificial intelligence also excludes the possibility that the introduction of AI systems in the healthcare system could «select and condition access to healthcare services according to discriminatory criteria» (Article 7, paragraph 2).

Given the numerous tasks that can be delegated to "thinking" machines, they could also be used to profile the patient in order to assess whether or not to offer access, making the eligibility judgment. However, this must be excluded, as, even in this case, the AI system can only serve as support and not as the exclusive decision-making center. The same applies when AI is used to define personalized information suitable for the personal, cultural, and vulnerability conditions of the specific patient: even here, the algorithm cannot go beyond its purely instrumental function, with the doctor being responsible for informing the patient to obtain their consent, fully aware of the

regulatory indication that «the time of communication between doctor and patient constitutes time of care» (Article 1, paragraph 8, Law n. 219/2017). Transparent information must be accompanied by empathy, which takes care of the patient's self-determination; this is true even when the patient refuses the telemedicine service, even if the AI systems used are particularly effective in realizing the patient's best interest. In fulfilling their duty to inform the patient «of the loss of opportunities» (Article 1, paragraph 5, Law n. 219/2017), the doctor must understand whether the refusal concerns the healthcare treatment itself or the technological tool through which it is provided, and, in the latter case, they must understand the reason; if the refusal is based on distrust of the technology, the doctor must face this by attempting to overcome any cultural or ideological barriers that might be behind it.

Thus, the *educational and supportive* role returns, involving multiple centers of responsibility, exceeding the boundaries of the care relationship and occupying areas that serve as prerequisites for access to "digital health", as a factor for the effective and free development of the person. These areas, if not supported by positive anthropocentric actions, ultimately threaten the preservation of the principles of democracy and the rule of law.

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