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*Public and Private Participation in Digitalised Healthcare**

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ABSTRACT The digitalization of health services does not represent a neutral revolution on the regulatory front. In fact, the new digital health will be increasingly populated by private actors, who might not be directly involved in the delivery of health services. In many cases, private entities are the mere holders and developers of the technologies and knowledge that enable the digital transformation of healthcare, without being involved in the care processes, unlike current affiliated healthcare professionals or private hospitals. The engagement of these new actors results in an increased use of soft law as a method of regulation, a trend that has been part of the healthcare system for long and is now being consolidated. However, at the same time a new trend is rapidly emerging: the engagement of private entities in the governance of a system that is becoming increasingly horizontal. This work describes the new relationships between public and private actors in the health sector under the perspective of regulatory requirements.

1. *Opening remarks*

Any reflection aimed at outlining possible future scenarios for a specific public policy area today must begin with an analysis of the contents of the National Recovery and Resilience Plan (henceforth also NRRP), which defines the reforms and investments eligible for funding under the *Next Generation EU Framework.*[1]

With specific reference to the health sector, the NRRP identifies four critical structural aspects of the National Health Service (NHS), which were already clearly evident at the onset of the pandemic: (i) the persistence of significant local disparities in the provision of services, particularly in terms of local prevention and assistance; (ii) a level of integration between hospital services, local services and social services that remains inadequate; (iii) long waiting times for the provision of certain services; (iv) a poor ability to achieve synergies in the definition of strategies for responding to environmental, climate-related and health risks.[2]

The response to these structural criticalities is defined in "Mission 6 Health" of the NRRP, which, in turn, is structured into two components, eight investment projects and two sectoral reforms. The plan for a new NHS outlined in Mission 6 is anchored on three main pillars: the strengthening of local-community care according to proposed organisational models and structures aimed at enhancing proximity of care and home care in particular; the promotion of innovation and digitalisation, also with a view to enhancing service provision by implementing remote-care practices (so-called telemedicine); support for research.[3]

Consistent with the global European recovery project, the achievement of these objectives and, ultimately, the revitalisation of the NHS is entrusted in large part – directly or indirectly – to the opportunities offered by technological development and digitalisation. It is no coincidence that the term "digitalisation" is used no less than nine times in the Mission 6 text, including once in the title of Component 2 – *Innovation, Research and Digitalisation of the National Health Service*, while the word *digital* appears 20

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[1] The Next Generation EU is the European Union's economic recovery instrument for Member Countries following the Covid-19 health crisis; it was enacted by Council Regulation (EU) 2020/2094 of 14 December 2020. The instrument is financed to the limit of EUR 750 billion at 2018 prices.

[2] NRRP, 225. The Plan also highlights that "The Covid-19 pandemic has confirmed the universal value of health, its nature as a fundamental public good and the macro-economic relevance of public health services. Overall, the National Health Service (NHS) shows adequate health outcomes and high life expectancy at birth despite the fact that healthcare expenditure relative to GDP is lower than the EU average".

[3] This summary is proposed by A. Pioggia, *La sanità nel Piano Nazione di Ripresa e Resilienza*, in *Giorn. Dir. Amm*., 2, 2022, 166. The Author proposes a critical analysis of the objectives of Mission 6, in particular highlighting the possible negative repercussions of the development of domiciliary care in terms of inequality. In this regard, see also G. Razzano, *La missione salute del PNRR: le cure primarie, fra opportunità di una "transizione formativa" e unità di indirizzo politico e amministrativo*, in *Corti Supreme e Salute*, vol. 2, 2022, 495 et seq.

times.

Digitalization, which is both a goal and a constituent element of each NHS development and relaunch trajectory, is also functional in ensuring the integration of successful health sector outcomes in the overall systemic recovery plan scenario.[4]

Albeit at the risk of excessive simplification – digitalised healthcare practices or "e-Health" can be identified with the application of ICT to the health sector in order to provide prevention, diagnosis and treatment services, monitor diseases and promote healthy lifestyles. But healthcare digitalisation is not limited to the spectrum of technology applications, it also underpins the innovation of services and how they are delivered. One of the most disruptive outcomes of what is already a manifestly advanced revolution is certainly the profound change it has brought about in the relationship between public and private health-service provision.

Indeed, digitalisation is populating the NHS with a multitude of private entities, owners, operators, and e-Health technology creators, not necessarily involved in healthcare provision, as are the private entities present in the system today: licensed healthcare facilities (clinics and nursing homes), affiliated pharmacies, private Scientific Hospitalisation and Care Institutes (in Italian, the IRCCSs – Istituti di Ricovero e Cura a Carattere Scientifico), affiliated healthcare professionals (General Practitioners and Primary Care Paediatricians).

Our public authorities are thus obliged to rethink a healthcare *governance* model built and consolidated on a public-private relationship paradigm that will soon no longer be the sole option. Sector regulation will, therefore, have to guarantee the NHS from interference by private interests other than the usual ones while simultaneously addressing old and new risks to patients, most notably the *cardinal risk*, namely the vulnerability of their privacy.[5] But as the State takes up its role as regulator of digital technology, it will also have to contend, not only in healthcare, with an unprecedented tendency of new private actors: the latter, in fact, by their sheer size, structural complexity, and the extent of the user base they serve, sometimes act as veritable public authorities in their own right, potentially in competition with the "official" ones.[6]

A struggling legislature[7] is thus facing the challenge of addressing innovation at a time when the NHS, weakened by more than a decade of spending restraint policies[8] and the pandemic, appears severely inequitable, in distress and exposed to new threats.

[4] The centrality of digitalisation is common to all the Missions. Article 18 of Regulation (EU) 2021/241 of the European Parliament and of the Council establishing the recovery and resilience mechanism, envisages that at least 20% of the National Recovery and Resilience Plan budgets must be invested to facilitate the digital transition or to deal with the resulting challenges (Article 18, par. 4, point f). Italy, which plans to allocate 25.1% of its total resources (approx EUR 48 billion) to digitalisation, has therefore adhered to this minimum with considerable margin.

[5] The expression is by C. Casonato. The Author highlights the ambivalence of some constitutional provisions that can promote new technologies and, at the same time, provide protection against their excessive or distorted use. "Thanks to the use of AI, in fact, an otherwise unmanageable volume of data can be processed quickly and accurately to configure highly detailed individual profiles. This clearly reveals the generalised risk of a widespread and pervasive intrusion into the most intimate spheres of each individual, with the risk of a blatant violation of the right to privacy and the exposure of highly personal information that could be used in multiple future situations, from mortgage applications to job interviews or the assessment of social dangerousness risk (the Italian "pericolosità sociale")". V. C. Casonato, *Costituzione e intelligenza artificiale: un'agenda per il prossimo futuro*, in *BioLaw Journal – Rivista di BioDiritto*, vol. 2, 2019, 719. This risk appears to be greatly amplified by the application of new technologies to the health sector, where much of the personal information processed relates to individuals' health and is, therefore, not only extremely sensitive but also the potential target of strong commercial interests.

[6] On this issue, the comment by Facebook founder and CEO Mark Zuckerberg is particularly insightful: "In a lot of ways, Facebook is more like a government than a traditional company". In an interview with journalist Ezra Klein, Zuckerberg he explains the meaning of his statement. https://www.vox.com/2018/4/2/17185052/mark-zuckerberg-facebook-interview-fake-news-bots-cambridge.

[7] Evidence of the difficulties faced by lawmakers in materially addressing technological-innovation issues is manifest in the generic character of the clauses contained in, for instance, Regulation (EU) 2016/679 (the so-called GDPR), Regulation (EU) 2022/2065 (the so-called Digital Service Act), and the proposed European Artificial Intelligence Regulation. This would allow a measure of regulatory free rein to private actors "[...] who are accorded sufficient leeway that, by establishing codes of conduct or standards, can produce legal effects both in respect of those who intend to adhere to them and those who do not". V.N. Maccabiani, *Co-regolamentazione, nuove tecnologie e diritti fondamentali: questioni di forma e sostanza*, in *Osservatoriosullefonti.it*, 3, 2022, 83.

[8] Cf. A Pioggia, *La sanità italiana di fronte alla pandemia. Un banco di prova che offre una lezione per il futuro*, in *Diritto pubblico*, vol. 2, 2020, 385-403.

2. *Public and private healthcare in "analogue mode": overview*

In a public-intervention context, healthcare has historically been markedly polarised, if not outrightly *conflictual*. With regard to the evolution of the entire welfare system itself: *"*on the whole, it has been influenced by three factors, with various degrees of conflict and integration applicable to the various cases: the interaction between the State and the Catholic Church; relationships between public and private sectors; and the relationship between the hub and the outlying structures of our political-administrative system".[9] Before examining the main changes that digitalisation is bringing to the framework of public-private relations, we should review the current situation also from a historical perspective.

Since its establishment by Italian Law no. 833 of 23 December 1978, the NHS has envisaged the coexistence of public and private healthcare providers. Over time, if anything, we have witnessed a change in the degree of integration of the private sector and its quantitative presence in a service that has retained its public character. The constitutional health protection programme itself, as defined in Article 32 of the Constitutional Charter, is fully compatible with such coexistence. The law specifically mandates the Republic to protect health, without, however, stipulating that services be public entities or allocating precise areas to their control, but instead leaving room for the development of mixed systems. It is quite true that public entities are called upon to intervene with greater responsibility.[10] Indeed, the presence of private providers could even be considered necessary because it is instrumental in guaranteeing patients the freedom to choose their healthcare practitioner and facility, between available modes of treatment and techniques, and between different care and rehabilitation programmes.[11]

The relationship between public and private actors in the healthcare system has undergone profound changes, coinciding with the key *institutional junctures*[12] of the NHS.

[9] G.L. Bulsei, *Il servizio sanitario nazionale tra decisioni politico-amministrative e pratiche sociali*, in R. Balduzzi (ed.), *Trent'anni di Servizio sanitario nazionale. Un confronto interdisciplinare*, Bologna, Il Mulino, 27.

[10] Cf. D. Morana, *Tutela della salute,* in G. Corso, V. Lopilato (ed.), *Il diritto amministrativo dopo le riforme costituzionali*, *Parte speciale*, vol. 1, Milan, Giuffrè, 2006, 266. On the same theme, see R. Ferrara, *Salute (diritto alla)*, in *Digesto discipline pubblicistiche*, Turin, Utet, XIII, 520, according to which "it would be plausible to believe that the Constituent Assembly wanted to outline and frame the healthcare-related duties of the Republic in the manner of other public functions, i.e. functions in the strict sense that cannot be divested since their exercise cannot be broken down into parts given that they are connected to and implicit in the very foundations and grounds of the welfare state based on the rule of law". See also the arguments posed by R. Balduzzi and D. Servetti. The Authors assert that "[...] the Republic's duty to safeguard its citizens as mandated by the Constitution is inalienable and, as such, the actions of public authorities in the field of healthcare override those of private interests [...]". V.R. Balduzzi e D. Servetti, in R. Balduzzi, G. Carpani (ed.), *Manuale di Diritto sanitario*, Bologna, Il Mulino, 26.

[11] Cf. F. Toth, *Le politiche sanitarie*, Roma-Bari, Laterza, 2009, 57. The Author focuses on how each healthcare model addresses a diversity of subjects and breadth. Following recent regulatory initiatives, freedom of choice is recognised as both an expression and consequence of the centrality that the legal system has acknowledged to the value of trust in the care relationship. Italian Law no. 217 of 22 December 2019 – *Rules on informed consent and advance medical treatment decisions* establishes the role of informed consent in healthcare. In Article 1, par. 2, it states that "the relationship of care and trust between patient and doctor is fostered and valued; it is based on the principle of informed consent, which jointly envisages the decision-making autonomy of the patient and the skill, professional independence and responsibility of the doctor. Healthcare professionals who make up the healthcare team contribute to the care relationship, according to their respective skills. If the patient so wishes, the relationship is extended to include his or her family members, civil partner or cohabitee, or a person of trust.". In the aftermath of the approval of the first law on informed consent in healthcare, it was asserted in the literature that "The reference to trust is important because it "enfolds", so to speak, the core of the care concept, and contributes to excluding any technical reductionism of the term "care" itself. Significant, albeit coincidental, is the repetition of the term "trust" for a different purpose in the remainder of the provision, which states that "If the patient so wishes, the relationship is extended to include his or her family members, civil partner or cohabitee, or a person of trust". Also this allowance for "inclusion" in the relationship helps to clarify the role of the patient's "carers" by establishing a "multiparty" relationship: which does impact the consequences for what we jurists refer to as the prerogatives of each individual". V. P. Zatti, *Spunti per una lettura della legge sul consenso informato e DAT*, in *La nuova giurisprudenza civile commentata*, vol. 1, 2018, 247.

[12] The expression was coined by A. Mattioni, who outlined the historical evolution of the NHS marked by its institutional junctures corresponding to the four national healthcare reforms: Italian Law no. 833 of 23 December 1978, Italian Legislative Decree no. 502 of 30 December 1992, Italian Legislative Decree no. 517 of 7 December 1993 and Italian Legislative Decree no. 229 of 19 June 1999. "Institutional innovation calls for a response that must empower an appropriate framework of healthcare governance, inclusive of new activities that can safeguard it and enhance its conceptual configuration [...]". This message can also apply today, at the

In the original scheme foreseen by NHS constituent law no. 833/1978, private providers were restricted to a function of mere support to public structures in the cases – which were expected to be rare – in which the latter would be unable to guarantee adequate coverage.[13] Indeed, the fruition of hospitals and outpatient facilities managed by the Local Healthcare Units (in Italian USLs – Unità Sanitarie Locali) was also promoted with a view to safeguarding and enhancing public investment while at the same time curtailing private entrepreneurial interests. This rigid original dualism, therefore, envisaged public-service provision under public administration governance, while private institutions could only enter as licensees of the service,[14] according to very strict entry rules.

This arrangement, as we know, was superseded by the reforms of the early 1990s (Italian Legislative Decree no. 502 of 30 December 1992 and Italian Legislative Decree no. 517 of 7 December 1993). The USLs were transformed into Local Health Enterprises (ASLs – Aziende Sanitarie Locali) on a provincial or sub-provincial basis and vested with organisational, administrative, financial, accounting, management and technical autonomy. In addition to providing healthcare, the ASLs were empowered to outsource services, thus extending their roles from mere "producers" to being "clients" of services as well. The essential levels of care would have been guaranteed not only by the operations of public facilities directly managed by the ASLs[15] but also by private institutions in return for the payment of scheduled fees for each type of service provided. Every patient would also have been guaranteed access to private providers, on condition that the latter were licensed, thus better guaranteeing individual freedom of choice (see Article 8-bis of Italian Legislative Decree 502/1992, as amended by Italian Legislative Decree 229/1999).

In a nutshell, licensing (or accreditation) entails a system whereby private facilities may provide services no longer only in their own name, but also on behalf of the NHS, within the limits set by sector planning and on the basis of specific agreements with the locally-competent health authorities, under the governance of the NHS: "In essence, the healthcare service should be managed according to a principle of fair competition between public and private entities".[16] The accreditation process imposes specific additional requirements beyond those mandated by the authorisation procedures applicable to licensees that establish and operate healthcare facilities; operators must comply with regional planning guidelines and successfully pass audits of their activities and achieved results.[17]

The public-private framework laid down in the 1990s remained virtually unchanged until the 1999 reform (Italian Legislative Decree 229 of 30 June 1999), which – as we know – completed the so-called corporatisation of

height of the digital revolution. V. A. Mattioni, *Le quattro riforme della sanità. Una lettura sinottica di snodi istituzionali*, in R. Balduzzi (ed.), *Trent'anni di Servizio sanitario nazionale. Un confronto interdisciplinare*, Bologna, Il Mulino, 2007, 263.

[13] V. A. Pioggia, *Diritto sanitario e dei servizi sociali*, Giappichelli, Turin, 2014, 123. On this subject, see also A. Catelani, *La sanità pubblica*, in G. Santaniello (ed.), *Trattato di Diritto Amministrativo*, vol. XIV, Milan, Cedam, 2010, 153-154.

[14] On this subject, see G. Corso, *Pubblico e privato nel sistema sanitario*, in G. Corso, P. Magistrelli (eds.), *Il diritto alla salute tra istituzioni e società civile*, Giappichelli, Turin, 2009, 19-20. According to the Author, "It is clear that the role of the private sector is marginal in this design".

[15] Paragraph 5 of the original version of Article 8 of Italian Legislative Decree 502/1992 laid down that the USLs assure citizens the provision of specialised services, including rehabilitation, instrumental and laboratory diagnostics, and hospital services by availing itself *"*of its own facilities, as well as of the enterprises referenced in Article 4 [hospitals], of public health institutions, including military or private hospitals, in addition to public facilities […]*"*.

[16] V. G. Fares, *Problemi attuali dell'ordinamento sanitario*, Editoriale Scientifica, Naples, 2012, 59. On the subject, see also, V. Molaschi, *Autorizzazione, accreditamento e accordi contrattuali tra esigenze di contenimento della spesa pubblica e tutela della concorrenza (Nota a Cons. Stato sez. III 16 settembre 2013, n. 4574)*, in *Giurisprudenza italiana*, vol. 3, 2014, 675; V. Molaschi, *Tutela della concorrenza, vincoli di spesa e rapporti tra Servizio sanitario nazionale e soggetti privati: una riflessione alla luce della modifica del titolo V della Costituzione (nota a TAR Lombardia, Milano, sez. I, 29 ottobre 2003 n. 4899),* in *Foro amministrativo TAR,* vol. 5, 2004, 1271.

[17] In its judgment no. 195/2021, the Constitutional Court described the system as follows: "The healthcare system, as reformed by legislative decree no. 502 of 1992 and then significantly remodeled by Italian Legislative Decree no. 229 of 1999, defines the public-private healthcare provision relationship according to a progressive system, on the basis of which entities intending to provide healthcare services must be authorised; if compliant with this as a prerequisite, they can apply for institutional accreditation, which renders them potential providers of healthcare services on behalf of the National Health Service. This step must be preceded by the stipulation of contracts with the administration and respect of the spending limits set out therein".

healthcare that had begun in the early years of the decade.

In the context of the new relationship briefly outlined, governance and regulatory efforts have been substantially oriented in two directions: on the one hand, to ensure that private providers functionally contribute to the fulfilment of the NHS statutory mission on the basis of the rules, especially regional rules, on accreditation; on the other hand, and to a preponderant extent, to control private expenditure, by means of a series of progressively-introduced mechanisms, including planning, expenditure limits defined for each provider,[18] and regressive rates,[19] to mention the main ones. Governance, therefore, has so far focused on two fundamental aspects: the entry of the private sector into the system and the control of the expenditure it generates. This mode of governance, however, is effective only on the condition that private entities provide healthcare.[20] The risk to be prevented or contained, in this case, is mainly the provision of inappropriate care, which in turn generates inappropriate expenditure, i.e. not properly invested in healthcare endeavour.

Acquired tools and expertise, therefore, cannot be exported *outright* to regulate the participation of new private operators who are not directly involved in care and assistance but who do possess knowledge, infrastructure and economic capacity for research and development in digitised healthcare.

The "accreditation system" and its general requirements, however, must be extended to the new digital health services and performances, in order to guarantee not only appropriateness and functionality with respect to the objectives of regional planning. The accreditation of digitised healthcare must, in fact, also be aimed at guaranteeing the technical safety of the services and the general compliance of the services with the regulatory apparatuses aimed at preventing the new risks: above all, the most relevant are those for the privacy of the patients and those for cybersecurity. The document "National Guidelines for the Provision of Telemedicine Services", approved by the State-Regions Conference with the agreement of 17 December 2020, contains some clear guidelines in this regard. Particular attention is paid to the technical training of personnel who will be responsible for providing telemedicine services: specific accreditation requirements are envisaged. A trained staff is certainly better able to contribute to the safety of the services.

3. *The private sector in the digital healthcare domain and the need for a new regulatory framework*

Whereas the contribution of private healthcare entrepreneurs could be regarded as supplementary to public provision (presumably capable of covering the need for healthcare), the participation of entrepreneurs from the digital sphere, on the other hand, is necessary: suffice it to mention the availability of data-storage infrastructure, an essential

[18] See recently, Campania Regional Administrative Court, decision no. 976 of 13 February 2023: "[...] the determination of expenditure caps is the expression of a regional planning power characterised by broad discretion in forecasting the extent and mechanisms for allocating the available resources, with the aim of balancing multiple and often conflicting interests of constitutional relevance, such as the containment of expenditure on the basis of the resources effectively available, the need to ensure quantitatively and qualitatively adequate healthcare services to patients, those of private structures operating on an entrepreneurial basis, and those of public structures tasked with providing services in compliance with the principles of efficiency and sound management".

[19] In Judgment no. 3809 of 20 June 2018, Section III of the Council of State asserted, "The regressive rate system implemented by the healthcare services (RTU – Regressione Tariffaria Unica) is the mechanism through which the Regional Authorities, called upon to plan and budget their relevant expenditure, ensure compliance with the ceilings assigned to them as well as overall organisational and financial stability. In other words, the "regression" mechanism enables the Regional Authorities to refund their treasuries with the monetary amounts related to healthcare services provided by accredited private facilities that exceed maximum limits established under the powers vested in public controllers of healthcare spending. It is therefore a method of final and contingent adjustment and rebalancing with respect to advance budgetary planning [...]".

[20] Private entities that are an integral part of the NHS also include General Practitioners and Primary Care Paediatricians. These professionals are retained under the affiliation system, which defines rights and obligations vis-à-vis the public service (organisation of outpatient activities, number of hours to be guaranteed, remuneration, incentives). Also in this case, private entities participate in the NHS and cater for a share of the healthcare provision. There is a high concentration of private entities within the pharmaceutical distribution network, which fully falls under the concept of healthcare. The reference is to privately owned local-community pharmacies, which are also affiliated to the SSN. Lastly, the private Scientific Hospitalisation and Care Institutes (IRCCSs), albeit pursuing research activities as one of their statutory purposes, are engaged in healthcare activities in the same way as hospitals.

resource for mechanisms such as the electronic health record (the Italian FSE – Fascicolo Elettronico) and the platforms that enable the provision of specific services. An excellent example of the aforementioned phenomenon is the recent commissioning of a National Telemedicine Platform by AGENAS, the National Agency for Regional Health Services, to a group of private companies, with the aim of creating "a fundamental level of interoperability capable of enforcing common standards for telemedicine services developed by the Regional Authorities, enhancing what is already available on a local level, supplementing or enhancing the range of provided services". In particular, the planning, implementation and management of the Enabling Services of the National Telemedicine Platform – sub-investment 1.2.3, within Mission 6 Component 1 of the NRP – were entrusted to a temporary consortium of companies that submitted a proposal following the call for expressions of interest published pursuant to Article 183, Paragraph 15 of Italian Legislative Decree No. 50/2016 (Public Contracts Code), which regulates so-called project-financing initiatives.[21] Private entities were therefore entrusted with the responsibility of implementing one of the most salient projects in the revitalisation of the NHS, telemedicine.[22] From a relational framework in which the NHS has always retained a pre-eminence and a dominant position over private actors (also from an ideological perspective), with the onset of digitalisation, the relationship is destined to develop on a basis of greater peer parity. In the absence of effective control and regulation, we could even see a gradual reversal of positions.

The new relationship between the public and private actors is affected by changes in another arena: the confrontation between the State and new technologies. Indeed, for the first time, the latter represent both "an intrinsic aspect of public power and a phenomenon whose regulation is central to economic and social relations as a whole".[23]

For some time now, technologies have been an integral part of the NHS and an integral part of the services provided, not only in the context of projects and activities officially headed by the public service. Also the private use of ICT tools, which has pervaded everyone's daily routine, in some cases synergises with the NHS, sometimes facilitating its operations, at other times supplementing them and improving their effectiveness. Possible ways of facilitating the relationship between users and the SSN include the use of instant messaging apps to dialogue with one's General Practitioner and to share reports and documents. The use of medical apps provided by private health centres, on the other hand, enables the tracing of patient care actions. By allowing their General Practitioners to access such data, patients enable them to supplement information already held by the NHS with that generated and stored by private providers, effectively creating a mixed public and private healthcare database.

The example of the Telemedicine platform,

[21] By resolution No. 423 of 11 October 2022, the National Agency for Regional Health Services (AGENAS) – in its capacity as the implementing party of the sub-investment Telemedicine, Component 1, Mission 6 Healthcare – called an open online tender procedure through the Net4market platform aimed at awarding a contract for the design, implementation, and management of the enabling services of the National Telemedicine Platform. The tender is covered by *project financing* pursuant to Article 183, par. 15 of Italian Legislative Decree 50/2016, with an estimated value of EUR 341,575,855.84 (excluding VAT). The procedure was closed on 8 March 2023 with the award of the contract by Agenas to the Temporary Enterprise Consortium (RTI – Raggruppamento Temporaneo di Imprese) Engineering Ingegneria Informatica S.p.A. and Almaviva S.p.A. The RTI will have to guarantee interoperability with the common components shared with the ESF 2.0 application architecture and with the Health Data Ecosystem, also with the goal of "facilitating the planning, governance and development of digital healthcare". Information on the procedure can be found on the institutional website of AGENAS, in the section "Calls for tenders and contracts": https://www.agenas.gov.it/bandi-di-gara-e-contratti2 (last consultation date: 26 March 2023).

[22] On the subject, see also, among others: C. Botrugno, *Un diritto per la telemedicina: analisi di un complesso normativo in formazione*, in *Politica del diritto*, vol. 4, 2014, 639-668; C. Botrugno, *La diffusione dei modelli di cura a distanza: verso un "diritto alla telesalute"?*, in *BioLaw Journal – Rivista di BioDiritto*, vol. 1, 2014, 163-175; C. Botrugno, *Telemedicina ed emergenza sanitaria: un grande rimpianto per il nostro Paese*, in *BioLaw Journal – Rivista di BioDiritto Instant Forum – Diritto, diritti e emergenza ai tempi del Coronavirus*, 2020; F. Gori, P.G. Macrì, S. Turco, E. Turillazzi, *Telemedicina: da emergenza a nuova normalità. Riflessioni medico-legali*, in *Responsabilità civile e previdenza*, vol. 2, 2021, 69. On the implications of Telemedicine in terms of professional liability, see F. Aperio Bella, *The Role of Law in Preventing "Remote" Defensive Medicine: Challenges and Perspectives in the Use of Telemedicine*, in *Federalismi.it*, vol. 1, 2023, 305.

[23] L. Torchia, *Lo Stato digitale. Una introduzione,* Bologna, Il Mulino, 2023, 19.

on the other hand, illustrates how public authorities and private entrepreneurs can and must collaborate in future scenarios.

Hitherto, the operations of private-sector service providers have been strongly affected by public administration prerogatives, such as determining the extent and types of services contracted, determining their suitability, and ultimately, using such leverage to influence the organisational arrangements of the private facilities themselves. This relational paradigm hinged on a substantively well-founded assumption, i.e. that public health authorities, partly owing to their accrued technical expertise (considering that these are the ASLs, the Local Health Enterprises), can be empowered to discretionally assess healthcare requirements with a view to, on the one hand, protecting the public status of the service and, on the other, containing the affirmation of extraneous private interests. As digitalisation advanced, the private sector stakeholders gained more weight in the relationship also by virtue of their technical expertise, aptitude for research and development, swiftness of response and, in some cases, their extraordinary financial resources.

It has been pointed out in scholarship that *"*in contexts characterised more by horizontal relational dynamics than by hierarchical interactions, and therefore more by participatory forms and output-derived procedural legitimation than by the rules of democratic political representation, it is equally true that in fields where governance prevails, soft regulation models find implementation*"*. The characteristics of so-called *soft law,* moreover, would be well suited to the dynamics of innovation, which are rapid and have very uncertain outcomes: *"*[...] as a potentially transitory mode of rule-making, halfway between the generic indication of policy lines and legislation, it may represent the best approach to tackle complex and diverse problems characterised by uncertainty".[24]

*Soft law, a "*convenient category that subsumes a world of regulatory ectoplasms*",*[25] englobes, among other things, the so-called guidelines, codes of conduct, good practices and standards. This corpus, although lacking the efficacy formally accorded to legislative enactments, is nevertheless capable of influencing the actions and behaviour of actors in certain specific sectors.

In the health sector, *soft-law* precepts have been adopted extensively for some time now, mainly due to the less rigid nature of the rule-forming process and the possibility of involving technical experts.[26]

[24] Similarly, E. Stradella, *La regolazione della Robotica e dell'Intelligenza artificiale: il dibattito, le proposte e le prospettive. Alcuni spunti di riflessione*, in *Media-Laws. Rivista di diritto dei media*, vol. 2, 2019, 78. The Author mainly addresses the themes of artificial intelligence and robotics, but these can extend to the broader scope of digitalization, in including the digitalization of healthcare. See also O. Pollicino, *I codici di condotta tra self-regulation e hard law: esiste davvero una terza via per la regolazione del digitale? Il caso della strategia europea contro la disinformazione online*, in *Rivista trimestrale di diritto pubblico*, vol. 4, 2022, 1051. The Author reviews, among other things, the debate on the regulation of the web, in particular highlighting its polarisation between two distinct positions which, in turn, emerge from two different traditions: on the one hand, the proponents of hard law in Europe and, on the other hand, the promoters of the use of soft law in the United States. The American debate, moreover, has seen the acknowledgement that "the peculiarities of cyberspace were not such as to distract the activities that took place there from any rules of conduct that had not already been introduced by states to govern the 'world of matter'*",* abandoning an initial almost anarchic position whereby the web was considered an unregulated space.

[25] Such ectoplasms are "endowed with varying degrees of regulatory power; where the intensity is not to be measured by the greater or lesser effectiveness of these disciplines, but is determined by the greater or lesser use of sanctioning instruments, falling under the traditional State monopoly*"*. See R. Bin*, Soft law, no law,* in *A. Somma, (*ed.), *Soft law e hard law nelle società post-moderne,* Turin, Giappichelli, 2009, 31-40.

[26] There are numerous examples of alternative regulation, included in the category of *soft law*, already used in the health sector. Among the most well-known and recent, see for example the document *National indications for the provision of telemedicine services,* approved by Agreement approved by the State-Regions Conference of 17 December 2020 (Register of Acts no. 215/CSR). On the regulation of Telemedicine via soft law enactments, please refer to M. Campagna, *Linee Guida per la Telemedicina. Considerazioni alla luce dell'emergenza Covid-19*, in *Corti Supreme e Salute*, vol. 3, 2020, 599. On the regulation of professional enagegment in healthcare, Law no. 24 of 8 March 2017, the so-called Gelli-Bianco bill, in Article 5 states that "Practitioners of healthcare professions, in the performance of healthcare services with preventive, diagnostic, therapeutic, palliative, rehabilitative and forensic purposes, shall comply, without prejudice to the specifics of the concrete case to the recommendations set forth in the guidelines published pursuant to paragraph 3 and drawn up by public and private bodies and institutions, as well as by the scientific societies and technical-scientific associations of the health professions registered in a special list established and regulated by decree of the Minister of Health, to be issued within ninety days from the date of entry into force of this law, and to be updated every two years. In the absence of the aforementioned recommendations, healthcare profes-

Thus, by favouring the use of *soft law* in all its manifestations (including self-regulatory scenarios), digitalisation could fuel the fragmentation of regulatory foundations in the healthcare sector, where governance has long been affected by considerable stratification and regulatory superfluity. The Covid-19 emergency, moreover, contributed to increasing the level of regulatory complexity: a crisis reaction mechanism, in fact, demanded the adoption of *"*a multiplicity of emergency measures, related to both healthcare and economics, [...] generating a veritable regulatory 'epidemic'".[27]

In confirmation of what has been argued here, the opinion of the Council of State (Consultative Section for Regulatory Acts) on the draft decree of the Minister of Health concerning the *Regulation on Models and Standards for the Development of Local Assistance in the National Health Service*, no. 881 of 19 May 2022, is of particular interest. This act is of fundamental importance for the implementation of healthcare-related NRRP initiatives. As we know, the scheme was then definitively approved and was incorporated into Italian Ministerial Decree No. 77 of 23 May 2022.

The Council of State noted that the Regulation submitted for its examination would have been superimposed on "a NHS regulatory framework that has been stratified over a long period of time, now measured in decades, and is highly articulated and complex in its sources, bodies, responsibilities and procedures". The proposed decree, therefore, would only have constituted "a further "regulatory layer" to the others, without replacing or even modifying them, only incrementally increasing the existing regulatory stock".

In this context, whereas soft law seems to be particularly suited to the regulation of technology and thus a somewhat inevitable solution, in literature,[28] it has also been pointed out how the assertion of soft law actually favours two trends: on the one hand, a shift of regulatory power from a national to a transnational domain, and, on the other hand, a contextual stakeholder shift from the public to the private sector (with reference to the phenomena of self-regulation and co-regulation).[29]

4. *Concluding remarks*

The healthcare digital transition is rapidly changing systemic relationships and relations: the relationship between public and private sectors is no exception. The new paradigm – anchored on balances of power and relationships that differ greatly from those of the past – calls for a regulatory framework that secures system governance, thereby updating and effectively implementing foundational NHS principles. This scenario is witnessing the consolidation of a trend that has long been present in the healthcare system, namely the use of *soft law* as a method of regulation. At the same time, however, a new trend is rapidly emerging: the involvement of private entities in the governance of an increasingly horizontal system.

The effectiveness of the new rules will be measured by their ability to provide a clear frame of reference "to enable the State and the

sionals should adhere to good clinical-care practices". Par. 3 of the same Article provided for the establishment of the National Guideline System, whose tasks and functions are regulated by the decree of the Minister of Health of 27 February 2018. The guidelines may be drawn up by public and private bodies, as well as by scientific societies and the technical-scientific associations of the health professions listed in the decree of the Minister of Health of 2 August 2017. Regarding the regulation of organisational models of significant importance for the NHS, we should mention the document "*Revision of the Organisational Guidelines and Recommendations for the Oncology Network that supplements acute and post-acute hospital activity with local activity*", approved with the Agreement approved by the State-Regions Conference on 17 April 2019 (Register of Acts no. 59/CSR). The Regional Authorities, to which the document is addressed, are required to implement the indications of Ministerial Decree 70/2015 – the so-called Hospital Standards – which establishes the rules for the construction of clinical-welfare networks, which include the oncology network. The proposed examples represent how acts with diverse names, but in any case not classifiable as hard law, have been used to regulate also very relevant aspects of the healthcare sector.
Among the numerous examples of alternative regulation concerning organisational models, see for example, the guidelines for the oncological network.

[27] Similarly, G. Napolitano, *Consiglio di Stato e qualità della regolazione tra pandemia e PNRR*, in *Giornale di diritto amministrativo*, 2022, 153.

[28] See again E. Stradella, *La regolazione della Robotica e dell'Intelligenza artificiale: il dibattito, le proposte e le prospettive. Alcuni spunti di riflessione*, 79

[29] On this subject, with particular reference to the European constitutional system, which has favoured the success of such instruments, see M. E. Bortoloni, *La regolazione privata nel sistema costituzionale dell'Unione Europea. Riflessioni sulla disciplina relativa al settore dell'innovazione tecnologica*, in G. Di Cosimo (ed.), *Processi digitali e tecnologie digitali*, Turin, Giappichelli, 2023, 63.

local authorities to adequately supervise the use of these laborious and sophisticated technological processes and tools designed by private entities, in order to remain as guarantors of the constitutional rights to health, social assistance and the principle of equality*",*[30] always ensuring that the use of the new technologies is consistent with the institutional mission of the NHS and that the latter's fundamental principles are respected.

Firstly, the ability of digitalisation to generate inequality is well known, albeit with a new trait. In fact, it does not depend on the level of wealth of individuals. The term "digital divide"[31] refers to existing differences in the possibility of using Internet services, due to age, the presence of adequate infrastructure, and digital culture. In healthcare, it means unequal access to new services, with effects that would compound the systemic structural inequalities. Efforts must therefore be directed at identifying solid equality safeguards that can withstand the pressure of digitalisation. The first obstacle to overcome will therefore be the operational adequacy of Essential Levels of Care (ELC). The procedure for their definition and renewal does not, in fact, appear to be entirely compatible with innovation time frames. Moreover, the structure of the measure that will define them, consisting essentially of a series of lists of services, could prove excessively rigid and unsuitable for configuring digital health services subject to rapid changes and uncertain classifications.

Regulatory interventions will have to act simultaneously on several levels. If one of the main causes of the digital divide continues to be poor knowledge of the new technologies,[32] the digital transition (not only in healthcare) will have to be accompanied by substantial investments in training and education, not only of patients, but also by intervening in schooling.

On the privacy front, the risk for health-service users appears to be much higher than the average risk associated with the use of technologies due to the particularly sensitive nature of the information processed in the provision of digitised care.

Lastly, due consideration must be given to the risk that private interests other than those for which various forms of protection have been developed over the years – such as systems to control the appropriateness of expenditure – will filter into the system, altering the character of the NHS as a public service.

In view of these risks, in the new relationship between public and private sectors – whatever system of regulation is chosen and whatever techniques are employed – the public authorities must resolutely pursue the balancing of diverse interests as an essential vehicle for adapting the framework of constitutional values to the existing and changing reality. This is an indispensable function for the resilience of the system, even when it develops horizontally and thus resistant to "imposed" regulation and more suited to governance by all actors. An effective solution in the management of digitalisation risks themselves can be found in the balancing of interests, which, on the other hand, directly contributes to the identification of such risks as they are directly represented

[30] See also E. A. Ferioli, *L'intelligenza artificiale nei servizi sociali e sanitari: una sfida al ruolo delle istituzioni pubbliche nel welfare italiano?*, in *BioLaw Journal - Rivista di BioDiritto*, vol. 1, 2019, 175. With specific reference to Artificial Intelligence, it has been pointed out in the literature that "the protection of rights appears, indeed, to be only one of the aspects in respect of which it is desirable that an evolution should take place that is capable of restoring a high level of control by individuals. From the perspective of public law, there are also requirements of governance of technology, which imply the need for regulators to implement appropriate forms of consultation at national and supranational levels". V. A. Pajno, M. Bassini, G. De Gregorio, M. Macchia, F. P. Patti, O. Pollicino, S. Quattrocolo, D. Simeoli and P. Sirena*, AI: profili giuridici. Intelligenza artificiale: criticità emergenti e sfide per il giurista,* in *BioLaw Journal - Rivista di BioDiritto,* vol. 3, 2019, 217.

[31] The digital divide "represents one of the most significant causes of social exclusion in contemporary advanced societies. The growing importance that the Web has acquired as an instrument of mediation of social relations makes it possible to configure the possibility of accessing the Web itself (and of conscientiously operating therein by fully exploiting the wealth of knowledge available) as an increasingly indispensable prerequisite for full participation in political, economic and social life and for the full development of the individual's personality. In this perspective – which primarily calls into question Articles 2 and 3, par. 2, of the Constitution – the victims of the digital divide suffer from an obstacle – the extent of which is increasingly manifest every day – that impedes the full development of individuals and deprives them of increasingly essential tools for exercising fundamental freedoms*"*. See also P. Zuddas, *Covid-19 e digital divide: tecnologie digitali e diritti sociali alla prova dell'emergenza sanitaria*, in *Osservatorio di Diritto Costituzionale*, vol. 3, 2020, 285.

[32] The report on the Digitalisation Index of Economy and Society (DESI), edited by the European Commission, notes for the year 2022 that in Italy, more than half of the citizens still do not even have basic digital skills.

in the regulatory texts.[33]

The real challenge therefore seems to be to "stop chasing and start leading", acknowledging that the digital revolution has already taken place. If this is the time for *design*, i.e., the time to define a human model for the digitalised world, the ultimate challenge lies in the governance of the digital reality (deciding what we want to do with it) and establishing methods and tools for its regulation.[34] The protection of health, given its centrality in the human journey, perhaps requires greater caution and urgent action. Precisely because of its inherent complexity, the healthcare system appears, once again, to be an extraordinary test bed.

[33]See, for example, the proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain legislative acts of the Union COM(2021)206 final. In the context of the proposal, it is quite clear that the goal of managing risks arising from artificial intelligence has permeated text drafting techniques and systems. On the subject, see C. Casonato, B. Marchetti, *Prime osservazioni sulla proposta di regolamento dell'Unione Europea in materia di intelligenza artificiale*, in *BioLaw Journal - Rivista di BioDiritto*, vol. 3, 2021, 415.

[34] Cf. L. Floridi, *Ethics of Artificial Intelligence*. *Developments, opportunities, challenges*, Milan, Raffaello Cortina Editore, 2023, 123 et seq. The Author, referring to all technologies and not only to AI, examines various regulatory drivers and makes a clear distinction between governance, regulation and ethics as they apply to digitalisation. The first "is the practice of establishing and implementing policies, procedures and standards for the correct development, use and management of the infosphere". Digital regulation, on the other hand, is "relevant legislation, a system of laws developed and enforced through social or governmental institutions to regulate the behaviour of relevant agents in the infosphere". Finally, digital ethics is "that field of ethics that studies and evaluates moral issues related to data and information (including generation, recording, curation, processing, dissemination, sharing and use), algorithms (including AI, artificial agents, ML and robots) and related practices and infrastructures (including responsible innovation, programming, hacking, professional codes and standards), in order to formulate and support morally good solutions, e.g. sound conduct or good values". It is thought to be digital ethics that would shape digital regulation and digital governance "through a moral assessment of what is socially acceptable or preferable". In a series of public statements, the author recently confirmed his position on the measure reported by the Italian Data Protection Authority on 30 March 2023 (Register of Measures no. 112 of 30 March 2023) which ordered the provisional restriction on the processing of personal data of data subjects established in Italy against OpenAI L.L.C., a US company that develops and operates ChatGPT, in its capacity as the data controller responsible for the processing of personal data carried out through that application. The measure caused a lot of uproar and triggered a lively debate on whether innovation should be impeded or, rather, governed by rules that incorporate ethical principles. See https://www.huffingtonpost.it/economia/2023/04/01/news/luciano_floridi_chat_gpt_garante_privacy-11725205/ (last consulted 1 April 2023).