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PROTECTING THE RIGHT TO HEALTH AFTER THE PANDEMIC EMERGENCY
Substantive protection and organizational dimension between territorial autonomies and the role of national-states

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INTRODUCTION TO THE RESEARCH

This research paper aims to analyze the difficult relationship between composite states and the protection of rights; a dichotomy that, according to some, is only apparent but which, when applied to the context of health protection, manifests itself in terms of a relationship that is difficult to define between the substantive protection of rights, which is the responsibility of the state, and the relative organizational structure designed to give it effective substance, in which local authorities play a leading role. The complexity of this context is further enriched by the currently necessary presence of a supranational institutional structure that is recognized as having the important task of protecting health, in its modern form as a global good, whose protection can no longer be relegated to a dimension strictly within individual national borders.

This is a scenario in which the state, compared to its traditional role as protector of citizens' rights, seems to be taking a back seat to sub- and supra-territorial entities, which appear to be acquiring the characteristics of instrumental and necessary structures for the protection of the right to health.

Starting from this consideration, it is necessary to emphasize the necessary and innate correlation between the substantive and organizational dimensions of the right to health to assess the actual impact of this multidimensionality of the institutional bodies entrusted with the task of protection. This is a complex dynamic, consisting of an interdependent relationship between the founding charters of the right to health and the structural apparatus set up by institutions to ensure its effective protection. Constitutions, ordinary laws, and supranational regulations intertwine to create a multi-level structure in which the recognition of a fundamental right is accompanied by the definition of complex inter-institutional and organizational relationships.

This dichotomy is reflected in the diversity of linguistic terms used to refer to health protection, to indicate situations relating to the fundamental individual right or the collective interest, and to healthcare, to indicate the complex of inter-institutional relationships and organizational structures set up for this task.

About the complexity of the institutional actors responsible for protecting and determining healthcare structures, it is appropriate to consider this complexity as a consequence of the socio-cultural changes that have characterized the context of Returning to the above statement recent years, which have contributed to determining a new physiognomy of the very concept of public health.
At the origins of its positivization, public health was defined as "the science and art of preventing disease, prolonging life, promoting, protecting, and improving health and well-being through the organized efforts of societies" (as stated in the WHO Glossary of Health Promotion), today, following the close interrelationship that has emerged between health and environmental issues, the very definition of health seems to have expanded into what is now referred to as "new public health." This formulation refers to a broad and forward-looking vision of this specific sector, which is characterized by a global consideration of the various innovative factors that can affect health, primarily environmental conditions.

After a tortuous path that follows the different historical periods in which the protection of fundamental rights has evolved, the protection of health, with the advent of democratic-social constitutionalism, has been identified and catalogued in the fundamental charters as an individual right, the effectiveness of which depends on political choices relating both to *the amount* of resources allocated to its protection and to how it is implemented.
From the first point of view, the right to health, understood as a social right to benefits, has significant consequences insofar as, by requiring the expenditure of public money, it becomes a key factor in the balancing act between the protection of rights and attempts to contain public spending.
Secondly, with regard to the actual methods of implementing this protection of the right to health, which is organized at different levels of government, the dynamics relating to it inevitably end up being interconnected with the structure of relations between the central state and local authorities.
The territorial organization of health care within composite forms of government aims to satisfy a dual need. On the one hand, it ensures centralized protection of the "core" of the right, which is due to every individual as a citizen, the effectiveness of which is considered not to depend on the different territorial location of

individuals. On the other hand, decentralized, territorially-based protection serves the purpose of bringing healthcare facilities as close as possible to the needs of individuals, identifying, at the level closest to citizens, the entity responsible for effectively meeting those needs.

Thirdly, the global dimension assumed by markets, which brings with it the movement of goods and people, inevitably requires a health protection system that necessarily transcends individual national borders. A system capable of reflecting the supranational scope that characterizes health, set in the current socio-economic context. In this context, therefore, the necessary limitation of the sovereignty of national states appears to be a necessary tool to ensure its protection. However, this necessity still clashes today with obstacles attributable to a more traditional view of state sovereignty.

Various solutions have been adopted in an attempt to balance the different interests involved—state, territorial, individual, and collective—whose resilience has been tested by the recent pandemic emergency, which, by causing a crisis in national health systems, has structurally and substantially changed the concept of health protection as understood in modern constitutionalism.

The Covid-19 crisis has had a profound structural and substantial impact on the health protection system. Not only has it thrown organizational structures into crisis, which have proved unprepared and unsuitable for managing a health emergency, but it has also prompted reflection on the need to reformulate the substantive protection of rights, confronting us with global and social changes in health, a commodity that is becoming increasingly connected to the environment and the ecosystem in which we live.

Based on the above considerations, the analysis will be structured as follows. Given the dual nature of health protection, the first part of this thesis will focus on the substantive protection of rights: a chapter dedicated to reconstructing the legislation aimed at positivizing the right to health, analyzing the different characteristics assumed by this position of advantage and their changeability over the course of different eras. This journey starts from the historically reductive view of health as a matter of public interest, typical of post-unification liberal legislation, passing through the mutualistic system typical of the fascist period, to the advent

of the 1948 Constitution, in which the positivization of the right reaches its peak through the multitude of subjective legal situations of advantage framed in the provision ofArticle 32 of the Constitution and supported by the principle of solidarity, which accompanies the individually identified advantages with the great duty of solidarity that permeates the entire constitutional text and underpins the entire system of rights.

The process of positivisation of substantive law culminates through its effective implementation 'through the National Health Service' established in 1978 by ordinary law, although considered constitutionally necessary in terms of content.

Today's regulatory context in which health protection takes place is characterized by a plurality of regulatory actors. Consequently, the protection of rights takes on a different form than in the past, no longer being reserved for the traditional monopoly of the national state, which often assumes the role of co-author or, in rarer cases, recipient of regulatory decisions taken at the supranational level.

This context also has an impact on the topic under discussion, so the second chapter will focus on analyzing supranational structures and related regulations designed to build a protection system that is capable of overcoming rigid national boundaries.

The paradigm shift in health protection requires a redefinition of its boundaries, which follow the trend of national sovereignty yielding to increasingly complex institutional landscapes. The speed of movement of goods and people that characterizes our historical era has led to talk of the globalization of health, whose dynamics require interventions that go beyond the rigid territorial boundaries of individual nations. This is the reason behind the presence and role of institutional actors such as the European Union, which in recent decades seems to have abandoned the exclusively economic focus that permeated its policies, placing increasing attention on the social dynamics of citizens; and also the World Health Organization, whose role is specified in the context of transnational health emergencies.

Following this substantive analysis, we will then move on to a study of the second dimension of law, namely the organizational dimension.

Territorial decentralization has accompanied Italian healthcare since its inception, and was soon accompanied, in chronological terms, by the issue of its financing. Faced with a universal and territorially structured healthcare system, a long period of reforms was undertaken to remodel and define the regional role that was gradually taking shape in the field of healthcare. On the other hand, the continuous growth of the deficit of public spending in the healthcare sector ( ) prompted the legislator to intervene on several occasions, mitigating the universalism of the original system.

A complex regional model that finds its balance and synthesis in the Essential Levels of a constitutional system of fundamental rights organized by territory. It has been reformulated several times and now seems to be under discussion once again: the very structure of territorial healthcare, which is the subject of the specific mission of the PNRR (National Recovery and Resilience Plan), and, on the other hand, the possible implementation of differentiated regionalism, which could once again call into question the already complex relations between the central state and local authorities.

In light of the analysis of the Italian model of healthcare organization, the model adopted by Spain will be proposed as a comparative study model. This is a model of state similar to the Italian one in terms of traditions and constitutional culture, but which differs partially from the latter in terms of the form of state. The Spanish system, characterized as an autonomous model of regional state, is composed of territorial communities whose recognized autonomy differs according to specific matters.

In light of a more in-depth study of the Spanish system and, in particular, the division of powers in the field of healthcare, we propose to understand how the change in the paradigm of relations between the state and the territories in the field of healthcare corresponds to a difference in terms of the protection, including substantive protection, of the right to health.

In conclusion, the last part of the thesis will focus on analyzing the recovery of the role of the national state in all cases where there is a danger of infringement of the right to health understood in terms of 'collective interest'. Starting from an analysis of the circumstances that have arisen following the spread of the Covid-19

virus, a comparative study will be proposed on how different legal systems have responded to the health emergency in terms of legislation. It will highlight common trends, such as the refocusing of interventions at the state level, derogating from the division of powers between the state and the territories, and the use of regulatory instruments managed mainly by the executive branch.

The recent pandemic experience shows us that the supremacy of the right to health justifies the use of emergency powers and, consequently, becomes a suitable reason for introducing derogations from the organizational structure established at the national level.

In light of the reconstruction of the legislative process aimed at enshrining the constitutionally relevant right to health and the organizational structure through which its protection is implemented , as well as the derogations introduced to deal with emergency situations, we will attempt, in conclusion, to define the relationship between organization and substantive protection, between healthcare and health in a post-emergency context that has profoundly changed its roots, necessarily supranational but traditionally of fundamental importance.

CHAPTER I

HEALTH PROTECTION: ORIGIN AND EVOLUTION OF A FUNDAMENTAL RIGHT

SUMMARY: 1. Introductory remarks. – 2. The evolution of health protection in the Italian legal system: health legislation from the unification of Italy to the Fascist period (1865-1934) – 3. The 1948 Constitution: the "many faces" of Article 32 of the Constitution. - 3.1 *Continued*. Health protection: a fundamental right. 3.2 Continued. The right to health as a financially conditioned right. – 3.3 *Continued.* Health protection: a subjective right and collective interest. – 4. The implementation of Article 32 of the Constitution: the National Health System. – 5. The new paradigm in health protection: the One Health approach.

1. *Introductory reflections*

The research aims to analyze issues related to health protection as a fundamental right of the individual, which, in today's world, is inexorably facing the need for redefinition in terms of content and organization as a result of the advancement and change of the social issues connected to it, but also, on the other hand, the need to redefine its organizational aspects inherent in the current historical context, characterized by crises and emergencies that are gradually losing their intrinsic exceptional nature, leading to what some define as an era of crises.

With this objective, it is useful to retrace the different historical and regulatory phases that have characterized health protection. In this specific context, emphasis should be placed on the different characteristics that protection and organization relating to the right to health have assumed throughout different historical periods. Starting from an analysis of the regulatory framework adopted in the liberal era, when health was protected only to the extent that it coincided with the public interest of the nation, we move on to the corporative vision typical of the totalitarian fascist state, a historical moment that also affected the mechanisms put in place to ensure and protect the individual and collective health of citizens, a symptom but also an instrument of the strength and greatness of the fascist nation.

An analysis of the constitutional provisions of Article 32 of the Constitution allows us to become aware of the distance and evolution of the legal system with respect to previous historical, h , and political eras. It is a complex regulatory reference whose literal wording reflects the complexity of the subjective and non-subjective legal situations it covers. Since its definition as a 'fundamental right', Article 32 of the Constitution has been the subject of debate in legal doctrine, which is still linked to the traditional conception of the rights of freedom typical of the liberal era as the only ones eligible for recognition as 'fundamental'.

This debate has been superseded by the realization that health is a prerequisite for the entire system designed to protect rights. Since the achievement of the assumption that the right to health, as a right to benefits, is a fundamental right, the prescriptive nature of Article 32 of the Constitution has been recognized, with the consequent need for a state law to ensure the satisfaction of the benefits required of the public system in order to ensure its full protection.

This requirement is reflected in Law No. 833 of 1978[1] , which established the National Health Service, whose principles of universality and equality soon came up against the difficulties inherent in the public financing of healthcare.

The healthcare deficit soon led to a series of reforms, starting with Legislative Decree No. 502 of 1992, aimed at stemming this problem by working, on the one hand, towards the corporatization of healthcare facilities and, on the other, towards strengthening the role of the regions; anticipating in this sense the regional development that the legal system would undergo a few years later following the reform of Constitutional Law No. 3 of 2001.

The complexity of health protection legislation is reflected in the multiple meanings that can be attributed to the concept of health as a legal right. Given that its meaning transcends that of mere psycho-physical integrity and is capable of encompassing an 'overall state of individual psycho-physical well-being'[2] , it is

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[1] “Ordinary constitutional implementation law” according to B. Caravita, *La disciplina costituzionale della salute (The constitutional regulation of health),* in *Diritto e società (Law and society)*, 1984; the author states that the principles underlying the reform are those of “respect for the dignity and freedom of the human person, the comprehensiveness, generality, and equality of healthcare services, and, ancillary to these, the principle of territoriality of services.”

[2] Again, B. Caravita, op. cit., on this point also M. Luciani, who, in identifying the object of health protection with individual psycho-physical integrity, including the adequate external conditions that allow it and therefore also the right to environmental health, postulates a broader concept than the

clear that such a broad concept with such flexible content cannot but be inevitably linked to changes in sensibilities and issues relating to the specific historical periods in which this discipline is embedded.

2. *The evolution of health protection in the Italian legal system: health legislation from the unification of Italy to the Fascist period (1865-1934)*

As previously mentioned, the polysemy of the right to health is reflected in the different historical phases in which its protection has taken place, which, alternating, have highlighted its different facets.

The first legislation relating to health protection can be found in the law 'For the Administrative Unification of the Kingdom of Italy', which also contained provisions relating to public health[3] .

The healthcare system did not enjoy true autonomy, as it was identified as a ministerial body, the latter being entrusted to agencies dependent on the Ministry of the Interior—such as prefects, sub-prefects, and mayors—and was organized according to a hierarchical system that aimed to achieve cooperation between the central government and the territories, based essentially on a complex system of central and territorial supervision. An element of continuity in Italian healthcare legislation, which, in its early days, provided for a Higher Health Council (CSS) at the top, which had advisory functions with regard to government action, assisted by Provincial Health Councils (CSP) and District Health Councils (CSD)[4] .

The original legislation on health protection had critical issues attributable to the ideology of the particular historical and political moment in which it was

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traditional object of protection provided for by the Civil Code in Article 5, leveraging the "favor personae that permeates the entire constitutional text," M. Luciani, *Il diritto costituzionale alla salute (The constitutional right to health),* in *Diritto e società (Law and society),* 1980;

[3] Reference is made here to Law No. 2248 of 1865, Annex C, whose provisions were supplemented by the enactment of the regulation of June 8, 1865, and the subsequent law of June 22, 1874, which extended to the provinces the possibility of imposing penalties for health violations.

[4] The functions of the Health Councils were governed by Articles 15-21 of the law and consisted of both public and private surveillance activities. Article 29 extended the surveillance powers of mayors to both public places, with regard to food and beverage inspections in commercial premises, and private homes, accompanied by the possibility of proposing measures to the authorities. see F. della Peruta, *Public Health and Health Legislation from Unification to Crispi,* in *Historical Studies,* 4/1980, pp. 713 ff.;

introduced[5] . Therefore, while it cannot be said that there was total disinterest and complete insensitivity to social issues, the legislation, a product of the liberal single-class state, took on characteristics that reflected at least a limited interest on the part of the institutions in meeting the social needs and demands of the community in terms of assistance[6] .

The reforms that followed during subsequent national governments were indeed motivated by the need to increase prevention and protection of the population's health, but they were always limited to a functionalist view of this subjective situation: the health of the population was of public interest insofar as it served the state's interest in ensuring its sovereign power. The proliferation of cholera epidemics and an infant mortality rate above the average for European countries at the time[7] led to the adoption of the first reform of the healthcare system, introduced by Law No. 5849 of 1888, known as the Crispi Reform.

Although the law was not particularly innovative in terms of healthcare organization, as this activity remained under the jurisdiction of the Ministry of the Interior, it did introduce innovations whose practical implications demonstrated the success of the regulatory intervention[8] , bringing the nation's mortality rate into line with that of neighboring European countries.

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[5] See F. Cammeo, *Public Health. General Principles, Sources, and Bodies of Health Administration,* in F. Cammeo, C. Vitta, *Public Health,* in V. E. Orlando (ed.), *Treatise on Italian Administrative Law,* vol. IV, part II, Milan, Società Editrice Libraia, 1905, 213 ff.;

[6] R. Ferrara, *Health (right to),* in *Digest of Public Law Disciplines,* vol. VIII, 1997, UTET, 514 ff.; in which the author, through a historical review, highlights how the modern concept of individual health protection is on a "collision course" with the welfare policies of the neo-unitary era of the nation, which are traced back to the different concept of Caritas as "a set of principles and rules that exclude any element of duty or obligation on the part of the public administration";

[7] see F.M.F. Melacrinis, *Quando la conoscenza guida l'azione politica: la legge Crispi-Pagliani del 1888 (When knowledge guides political action: the Crispi-Pagliani law of 1888),* in *Studi* Politici, 2/2024; in which the author points out that, before the unification of the Kingdom, Italy had a mortality rate of 30.9 per thousand inhabitants, compared to France and England, which had rates of 21.7 and 21.4 per thousand inhabitants respectively; even after unification, the infant mortality rate in 1863 was 48.8% in the first five years of life;

[8] In particular, the law, consisting of only a few articles, merely affirmed the need for technical staff in central offices and prefectures, establishing the figure of the provincial doctor at the peripheral level. There were few innovations concerning the spread of contagious diseases, providing for a series of fines for offenders and leaving more specific rules to the implementing regulations. No mention was made of the Public Health Directorate, which, although it existed, lacked effective autonomy, being part of the Ministry of the Interior. Among the most significant innovations, it is worth highlighting the implementation of technical and scientific professionals within institutional organizations, provisions aimed at combating infectious diseases, and the implementation of a territorial surveillance network, cf. M. Di Simone, *Health Policies in Italy from Crispi to Giolitti. Research paths in the papers of the Central State Archives,* in *Popolazione e Storia,* 1/2002, p. 143

The true innovative scope of the law becomes clear when one considers the silence of the fundamental text – represented by the Albertine Statute – which made no mention of the right to health. In the newly formed nation, which at the time was plagued by epidemics caused by poor public and private hygiene, healthcare was regulated by ordinary laws issued by Parliament, which attempted to combine a multi-level organization – between the center and the territories – but which suffered from a reductive view of what is now considered a 'fundamental' right, which at the time was seen as a mere public interest, typical of the liberal ideology that characterized the historical period in which the Statute was introduced; in this historical phase, institutional interventionism was not aimed at the subjective dimension of the right to health, as the latter was configured exclusively as a public interest, insofar as it was in the interest of the State that the population be healthy. According to the doctrine of the time, the public health system was limited to three essential areas: the administrative aspect, regulating relations between the central state and peripheral administration, which was also entrusted with the task of defining the supervisory function; a negative aspect of a police nature, concerning coercive measures aimed at preserving public health; and an organizational aspect[9].

The innovative scope of the Crispi law is particularly noteworthy from this point of view; it marks the moment when the state—albeit with the limitations of the time—took on the task of protecting the health of its citizens. In particular, the 1888 legislation distanced itself from the various draft laws discussed by previous governments[10], which were inspired by the principle of absolute limitation of state interference 'with the free exercise of property and individual rights', going so far

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ff.; G. Ognibeni, *Legislazione e organizzazione sanitaria nella seconda metà dell'Ottocento,* in M.L. Betri, A. Gigli Marchetti (eds.), *Health and the Working Classes in Italy from Unification to Fascism,* Angeli, Milan, 1982, 583 ff.; G. Vicarelli, *The Roots of Health Policy in Italy, Society and Health from Crispi to Fascism,* Il Mulino, Bologna, 1997;

[9] as stated by F. Cammeo, *Public Health,* op. cit;

[10] reference is made here in particular to the draft Health Code – drawn up by the Commission appointed by lieutenant decree on September 12, 1866 – approved by the Senate on May 1, 1873, but which never passed the scrutiny of the Chamber of Deputies because it was contrary to the provisions contained therein relating to the composition of Health Councils; see Parliamentary Proceedings, Chamber of Deputies, 1871-1872 session, second of the 11th Legislature, document no. 223;

as to affirm the new principle that 'it is the duty of the state to protect public health'[11].

The first comprehensive legislation on health matters dates back to the Consolidated Law on Health of 1907, which was composed of the original 1888 regulations and the subsequent laws no. 460 of 1901 and no. 427 of 1902[12]. Although incomplete in some respects, it constituted an important step forward in health protection. The Consolidated Law, issued during the Giolitti era, while complying with the organizational and structural principles outlined by the Crispino laws, was the manifesto of "a policy that, for the first time, provided for direct state intervention on an entire population at risk"[13] aimed at improving the health and hygiene standards of a population ravaged by malaria.

The organizational structure of healthcare, outlined during the liberal era, was divided into a tripartite system in which the central, hierarchically superior apparatus was followed by the territorially competent structures subordinate to it[14], which were flanked by the so-called Opere pie, charitable institutions that, following the law of 1890, were publicized and thus removed from the hegemony of the Church. In this way, the assets of ecclesiastical bodies were exploited, while the intervention of state institutions in purely social matters remained limited.

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[11] F. Taroni, *Healthcare in Italy from Unification to the National Health Service,* in *Critical Manual of Public Health,* Maggioli, Rimini, 2011;

[12] The regulatory shortcomings of the healthcare reform introduced by the law of 1888 became apparent with the increase in epidemics within the peninsula, which led to a proliferation of legislative initiatives through which, for the first time, public institutions took on the task of protecting the right to health, understood no longer only as a right of freedom, but also as a right to healthcare services. Particularly relevant is the provision of Article 3 of Law No. 57 of 1904, which introduced the obligation for municipalities to provide, in addition to healthcare, free medicines to the poor; see A. De Bernardi, *Pellagra, Stato e scienza medica: la curabilità impossibile,* in F. Peruta (ed.), *Storia di Italia, Annali 7, Malattia e medicina,* Einaudi, Turin, 1984, pp. 681 ff.; V. Fargion, *L'assistenza pubblica in Italia dall'Unità al fascismo: primi elementi per un'analisi strutturale,* in *Rivista trimestrale di scienza dell'amministrazione,* 1983, 30, pp. 25 ff;

[13] F. Taroni, op. cit.;

[14] According to F. Cammeo, "*legislative provisions on health matters dictate only the general principles of the health legal system. They are supplemented by a very broad regulatory power of the administrative authority at all levels, from the central government to prefects, provinces, and* municipalities"; the author justified the breadth of administrative regulatory powers in this area on the basis of its specificity, technicality, and changeability, asserting that "*it is a technical matter that is easily changeable according to discoveries in medical science and the unpredictable variability of health conditions from moment to moment following the outbreak and spread of certain diseases (...) and the diversity of soil and housing hygiene conditions in different parts of each* country"; adding that *"it is legitimate in health matters, which cannot easily be linked to political or party issues, prejudices, or tendencies, to leave greater latitude to the administration in general and to the government in* particular"; in F. Cammeo, *Public Health,* op. cit;

Mutual assistance arose during the Fascist period, whose ideology was based on the inclusion of all corporations in the regime's founding ideology. Although the underlying ideology was borrowed after the First World War and with the advent of the Fascist regime, the healthcare system remained unchanged by liberal legislation, but was flanked by various welfare organizations. Particularly significant was the Labor Charter issued in 1927, which contained a social insurance program concerning "the improvement of insurance against accidents at work and voluntary unemployment; the improvement of maternity protection; insurance for occupational diseases and tuberculosis as a start to general insurance against all diseases," whose most innovative tool in this regard was the establishment of "mutual health funds" provided for in collective labor agreements[15] .

A distinctive feature of fascist legislation was the attention paid to social issues, which was translated into the establishment of social security institutions, always with a corporate spirit, which dealt with salient and specific issues and problems aimed at satisfying the needs of the community: in particular, between 1933 and 1935, two important social security institutions were established, namely the National Fascist Social Security Institute and the National Fascist Institute for Insurance against Accidents at Work, while the law of January 1943 established the third important Fascist social institution, namely the National Health Care Institute.

The overall picture outlined by the second consolidated text of health laws[16] did not stray too far from the previous liberal legislation: it continued to be a complex, highly hierarchical system in which the ministerial coordination office, assisted by a surveillance network under the administration's jurisdiction, was subordinate to the auxiliary technical bodies. The healthcare organization continued to be fragmented due to the existence of national works or social security institutions which, unlike in the previous era, despite being 'incorporated' within the

[15] See M. Morello, *La tutela della salute e della sicurezza sul lavoro nell'Italia fascista (The protection of health and safety at work in Fascist Italy),* in *Quaderni di Diritto della Sicurezza sul lavoro (Workplace Safety Law Notebooks),* 1/2024

[16] Law No. 1265 of July 27, 1934;

nation, constituted a second alternative channel to that headed by the Ministry of the Interior[17] .

The distinction between the regulations adopted in different eras is not so much evident in the content of the provisions contained therein, but rather in the ideology from which they originate. While institutional interventionism—albeit minimal—in the health sector, as envisaged in the liberal era, was supported by the need to protect the population through measures aimed at bringing hygiene and health standards, and consequently the mortality rate, into line with the European average, as a matter of public interest for the state, this took on a slightly different form during the fascist era, when the health and well-being of the population was identified with the nation's power index, the public entity that encompassed every individual, social and institutional formation in a struggle for supremacy over the outside world.

The protection of health itself was therefore functional to the construction of an omnipotent nation and any present that could prevail over any (ideal or real) enemy force.

3. The 1948 Constitution: the 'many faces" of Article 32 of the Constitution

From a purely historical point of view, it is clear that the Italian Constitution approved and enacted in 1948 represents a political manifesto that is concerned with distancing itself from the political ideologies that preceded it, not only with respect to fascism, from which it expressly differs, but also with respect to liberalism, presenting itself, with respect to the latter, as an evolutionary development, particularly with regard to the protection of individual and collective rights.

The main changes brought about by the 1948 Constitution do not only concern the form of the state, which, following the historic constitutional

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[17] A. Simoncini, E. Longo, *Article 32,* in R. Bifulco, A. Celotto, M. Olivetti (eds.), *Commentario alla Costituzione,* vol. I, UTET Giuridica, Turin, 2006, 657 ff.;

referendum, is configured as a democratic republic, but they are also significant from the point of view of the protection of rights.

The centrality of the personalist principle in this renewed context gives rise to the explicit provision of the obligation on the part of institutions to identify and eliminate any 'obstacle' that stands in the way of the full realization of the individual, which translates into the consequent duty to implement policies aimed at effective protection of rights.

Social rights, or rights to benefits, arise from the provision of these *obligations* on the part of the State.

A constitutional evolution that leads to the affirmation of the welfare state as an advanced form of the rule of law, from which it differs in part, while drawing its origins from it[18] . The differences between the two different forms of state do not concern so much the quantity of social services provided by the institutional apparatus, but rather the different attitudes of the institutions. While in the liberal era, state interventionism was expressed through various "functions"[19] assumed by the state in order to protect public and collective interests, it was only with the advent of the social-democratic form of state that it became possible to recognize an effective obligation to guarantee the protection of rights defined as fundamental by the constitutional charters themselves.

Health protection is included in this complex and revolutionary regulatory system, as the Italian Constitution is "the only contemporary constitution to provide comprehensive regulation"[20] . The original wording was not without criticism, based on the (considered) excessive generality of the formulation of health as a 'fundamental right of the individual' and as a 'collective interest', thus preventing a

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[18] M.S. Giannini, *Welfare State,* in *Scritti Mortati,* vol. I, 1977, Milan; E. Forsthoff, *The Rule of Law in Transformation,* Milan, 1973; E. Ferrari, *Social Services,* vol. I, Milan, 1986; M. Mazziotti di Caleso, *Social Rights,* in *Enc. Dir.,* 1964, 806 ff.; M. Luciani, *On Social Rights,* in A. Pace (ed.), *Studies in Honor of Manlio Mazziotti di Celso,* Padua, 1995 119 ff.; A. Baldassarre, *Social Rights,* in *Enc. Giur.,* XI, Rome, 1989, 29 ff.;

[19] see R. Ferrara, *Health (right to),* op. cit.;

[20] C. Mortati, *La tutela della salute nella Costituzione italiana,* in *Scritti,* vol. III, Giuffrè, Milan, 1972, p. 433 ff.;

complete qualification of the legal situation underlying it[21] and, on the other hand, on the breadth of the promises that 'the Republic' made to the community[22] .

The innovative scope of the provisions of Article 32 can, in fact, be understood in two ways: on the one hand, in terms of political and social changes and, on the other, from a purely legal point of view.

With regard to the first aspect, it proclaims the commitment undertaken by the Republic to assume the obligation to guarantee the protection of health, announcing a Copernican shift from the previous liberal regime[23] ; from a second point of view, the wording linking two different subjective situations of 'individual right' and 'collective interest' relativizes the theoretical boundaries aimed at distinguishing between programmatic and prescriptive rules, confusing the content of the right with the instruments aimed at implementing it[24] .

The literal wording of the constitutional text shows that the provision in question combines a number of totally heterogeneous textual formulations that allow for the identification of an equal number of legal situations[25]. This provision gives rise to a complex system of regulatory references, which has resulted, on the one hand, in slow implementation due to a traditional doctrine that, for a long time, continued to recognize it as merely programmatic in nature and, on the other hand, following a complex development of case law, in the elaboration of a series of legal situations[26].

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[21] cf. F. Sullo, *"In this first part of the draft Constitution, there are two categories of rights: rights of freedom and social rights (...) this Article 26 (*originally the provision establishing the right to health) *does not in fact affirm either rights of freedom or social rights,"* session of April 24, 1947, A.C., II, 1214;

[22] N. Iotti defined the promises of protection guaranteed by the provision – at the time still in the draft stage – relating to the protection of health as "*empty* promises", given the state of public hospitals and the hygienic conditions of the population; N. F. S., session of April 19, 1947, II, 1034;

[23] *'Article 32 was designed solely for the purpose of affirming and establishing traditional legal situations in order to mark and graphically signify the transition from a model characterized by the absolute indifference of public authorities (...) to a system in which the positive intervention of the welfare state is considered necessary and obligatory'*, according to R. Ferrara, *Salute (diritto alla) [Health (right to)],* op. cit., p. 525;

[24] "*Health, unlike other constitutional rights, cannot be traced back precisely to an action or inaction, to a legal or material activity; it is, in reality, a state, that is, a certain condition of well-being to be preserved over time*," according to A. Simoncini, E. Longo, *Article 32,* op. cit.; on the evolution of the concept of health, see also R. Cesana, *Il Ministero della Salute. Note introduttive alla medicina,* Florence, 2001;

[25] M. Luciani, *Il diritto costituzionale alla salute (The constitutional right to health),* in *Diritto e Società (Law and Society),* 4/1980, CEDAM, 770ff;

[26] Health is in fact literally qualified as a fundamental right, and the recognition of health as an individual subjective right is also undisputed; the tenor of the provision under discussion is not

3.1 Health protection: a "fundamental right"

Firstly, the very decision to define the right to health as 'fundamental' has not been without criticism: the doctrinal debate focused on the compatibility of this association, given that the right to health, as a social right to benefits, could not assume the same status as a fundamental right, traditionally reserved for the more classic rights of freedom[27] .

A subsequent development, which gained ground thanks to authoritative doctrine[28] , led to the elaboration of an orientation contrary to the previous one, leveraging the incessant evolution of law and the protection of fundamental rights.

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limited to subjective positions of advantage, since the provision contains references to situations of obligation insofar as the same good is defined as "in the interest of the community"; the wording of the provision also lays down the conditions for identifying a right to benefits insofar as it establishes that 'free treatment for the indigent' is guaranteed; provisions establishing negative freedoms where a limit is placed on the public authorities, which may not compel any individual to undergo certain treatments except by law, also directly establishing binding principles for the latter, as it is required that such law not conflict with the limits of respect for the human person;

[27] M. Luciani speaks of "irreconcilable incompatibility between the different principles on which the two categories of rights are based" with regard to the path that led to the affirmation of social rights; in M. Luciani, *Il diritto costituzionale alla salute (The Constitutional Right to Health),* op. cit., p. 771;

[28] Part of the doctrine, in fact, denied social rights the same dignity recognized to rights of freedom, leveraging the conviction that less value was attributed to the constitutional principle from which they were believed to originate. The ideology of the liberal tradition, not yet completely overcome, was based on the division between the two fundamental principles of the Charter from which the different categories of rights sprang. On the one hand, there was the principle of freedom, which underpinned the fundamental rights of civil liberty, alongside the different principle of equality[28] which, in its modern sense of substantive equality, commits the State to take action to ensure the effective protection of those rights whose enjoyment is subject to *action* on the part of the institutions[28] .

This contrast was overcome in the years following the entry into force of the Constitution, whose provisions gradually became the cornerstone of the renewed constitutional fabric of the legal system. Among these is the central importance that the Constitution attaches to the principle of personalism, a cornerstone of the entire constitutional fabric[28] , which has led legal scholars to affirm the need not to limit human beings to an abstract dimension but rather to place them in the context in which they live[28] . From a purely theoretical point of view, a further critical argument against the above thesis was based on the fact that the incompatibility between freedom and equality was founded on the erroneous assumption that the evolution of rights came to a halt with the liberal era, as a result of the bourgeois struggle against state power, which had achieved the definitive recognition of fundamental freedoms; thus halting the evolutionary process of the protection of rights at an era that had already ended. ; see on this point M. Luciani, *Il diritto costituzionale alla salute,* cit., 773; H. P. Schneider, *Caratteri e funzione dei diritti fondamentali nello Stato costituzionale,* in *Diritto e Società,* 2/1979, 220 ff.; N. Bobbio, *L'età dei diritti (The Age of Rights),* Turin, Einaudi, 1990; M. Fioravanti, *Appunti di storia delle costituzioni moderne. Le libertà fondamentali (Notes on the History of Modern Constitutions. Fundamental Freedoms),* 3rd ed., Turin, Giappichelli, 2014; G. Oestreich, *History of human rights and fundamental freedoms (1978),* G. Gozzi (ed.), Rome-Bari, Laterza, 2001;

The concept of generations of rights[29] began to be discussed to affirm not only that more recent rights had equal dignity to those traditionally affirmed, but also the logical and chronological link that connected the different "generations of rights" according to which the most recent ones originated from the previous ones.

Having thus arrived at the peaceful traceability of the different categories of rights, which, although established in different historical periods, belong equally to *the genus* of fundamental rights, the doctrinal orientation that developed with the emergence of pluralistic democratic constitutions is that aimed at identifying the two-dimensionality of rights[30] . No longer traced back to different 'categories-generations', but as a single entity characterized by a multiplicity of facets.

This argument, although particularly opposed by more traditional doctrine, is particularly relevant in the specific field of health protection. The negative dimension, which expresses the defensive nature of the right on the part of individuals, is accompanied by the positive dimension, which requires state intervention to make the protection of this right effective[31] .

The negative dimension, which in the study of the right to health as a fundamental right takes the form of the state's duty of abstention in the individual sphere, specifically linked to the possibility of recognizing individuals' 'right not to be treated' or 'right to freely choose one's doctor', outlines traditionally understood subjective positions of advantage, which imply the removal of state impositions where these are potentially incisive in the sphere of healthcare self-determination . [32]

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[29] P. Ridola, *Fundamental Rights: An Introduction,* Turin, Giappichelli, 2006; A. Barbera, C. Fusaro, C. Caruso, *Course in Constitutional Law,* Bologna, Mulino, 2024:

[30] A. Di Martino, *The Dual Dimension of Fundamental Rights,* in *Rivista del Gruppo di Pisa,* 2/2016;

[31] "the right to health, in accordance with the constitutional precepts that entrust the Republic with the task of protecting it as a 'right of the individual and interest of the community', would assume a force almost analogous to that of traditional individual freedoms: and this not only from a negative point of view (i.e., with regard to the exclusion of compulsory health treatments) (...) , but also from a positive/negative perspective (i.e., the right to protection erga omnes in relation to situations that are potentially harmful to health), to arrive at the purely positive value of the right, (...) in relation to the protection provided for in ordinary legislation, in the form of the right to receive appropriate care services to protect the psycho-physical integrity of the person." according to R. Nania, *The right to health between implementation and sustainability,* in M. Sesta (ed.), *The provision of medical services between the right to health, the principle of self-determination, and the optimal management of healthcare resources,* Rimini, Maggioli, 2014;

[32] G. Baldini, *Reflections on Bio-law. Evolutionary profiles and new issues,* Milan, 2019; P. Veronesi, *Features and limits of the fundamental right to self-determination,* in *Riv. Biodiritto,* 2019 no. 27;

Healthcare self-determination enjoys constitutional significance insofar as this subjective situation is linked to the provisions of Article 32 of the Constitution, both because it is characterized as a fundamental right and because, in the second paragraph, the same provision subordinates the imposition of healthcare treatments to specific legal provisions[33] . Although even today the right to life[34] , and relatedly the right to health understood as physical integrity, is considered an inalienable right for the individual concerned, numerous steps forward have been taken by case law[35] and legislation[36] , leveraging the ever-increasing importance attributed to individual self-determination.

The difficulties in bringing to the fore the self-determination dimension of the right to health, which still exist today, can be traced back to the intertwining of this component with bioethical issues and deeply rooted cultural beliefs; hence the difficulty with which Parliament is attempting to respond to the innovative needs

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[33] *infra* § 4.3;

[34] Although the Italian Constitution of 1948 did not explicitly provide for the right to life, the latter nevertheless obtains constitutional recognition through Article 117(1) of the Constitution as a provision requiring compliance with obligations arising from the Union and international bodies, including the European Convention on Human Rights, Article 2 of which explicitly recognizes and protects the right to life; Furthermore, through interpretation and case law, the right to life has been traced back to the provisions of Article 2 of the Constitution. The "fundamental good of life (...) is the first of the inviolable rights of man recognized by Article 2 (Constitution)" C. Const. ruling no. 223 of June 27, 1996;

[35] *Ex plurimis C.* Cost. judgments nos. 5/2018; 268/2017; 218/1994; for a commentary on the doctrine of self-determination in healthcare, see Spataro, *Law no. 219 of 2017 and the regulation of end-of-life issues between constitutional principles and unresolved problems. Food for thought,* in *Riv. Biodiritto,* 2/2019; F. Minni A. Morrone, *The right to health in the jurisprudence of the Italian Constitutional Court,* in *Rivista AIC,* 2013; G. Battistella, *The right to medical assistance in dying between the 'constitutionally obligatory' intervention of the Judge of Laws and the discretion of Parliament. Food for thought on the legislative follow-up,* in *Osservatorio AIC,* 1/2020; M. Cartabia, *Constitutional jurisprudence relating to the second paragraph of Article 32 of the Constitution,* in *Quad. Cost.,* 2012; V. Gastaldo, *Compulsory health treatments and the Constitution. The case of mental health,* in *Riv. Biodiritto,* 2/2019; M. Nocelli, *Authority and freedom in healthcare decisions between the principle of solidarity and the principle of personalism,* in *giustiziaamministrativa.it;* G. Baldini, *Reflections on Bioethics. Evolutionary profiles and new issues,* CEDAM, 2019;

[36] in this sense, Law No. 219 of 2017, which provides for and regulates 'informed consent' as the essential cornerstone on which the possibility of exercising self-determination in the healthcare field is based, this institution is defined by the Constitutional Court as 'conscious adherence to the healthcare treatment proposed by the doctor (which) constitutes a genuine right of the individual and is based on the principles expressed in Article 2 of the Constitution, which protects and promotes fundamental rights, and in Articles 13 and 32 of the Constitution, which establish respectively that 'personal freedom is inviolable' and that 'no one may be obliged to undergo medical treatment except under the provisions of the law', according to Constitutional Court ruling no. 438 of December 23, 2008; see S. Canestrari, *Informed consent and advance treatment provisions: a 'good law',* in *Corr. Giur.,* 3/2018;

of the community[37] . The Court's words show that, although recognized, the right to self-determination is in reality relative and, to some extent, recessive with respect to certain constitutional rights[38] . This results in a limitation of the negative obligations of the State; the right to self-determination cannot go so far as to include a complete and total choice about one's destiny and individual life, but must be balanced with objective criteria, including the state of illness[39] .

In light of these – albeit brief – reflections, it seems possible to say that, although the 'defensive side' of the law is the one that has historically been given the most importance, the negative dimension of the fundamental right to health, which presupposes the obligation of abstention on the part of the public authorities, does not express its full potential. Healthcare self-determination as a limit to state imposition in medical matters does not have a significance that can be defined in absolute terms, since the limit of abstention lies not only where there are equally

[37] Emblematic in this sense is the case of so-called assisted suicide, or the legitimacy of active euthanasia practices, which brought the question of constitutional legitimacy to the Constitutional Court for the first time in 2018. The Council, in an innovative ruling, initially referred the matter back to the legislature through a suspension order of the constitutional proceedings, pending action by Parliament given the sensitivity, relevance, and impact of the issue in the context of collective rights. The failure of the legislature to act led the Court to issue an additional ruling listing the cases in which assisted suicide practices are not punishable under Article 580 of the Criminal Code, which punishes aiding suicide. On this matter, see A. Ruggeri, *End of life (problems and prospects),* in *Consulta online,* 1/2023; A. Ridolfi, *Is the right to die a constitutionally protected right? (Considerations based on the Cappato-Antoniani and Trentini cases),* in *Costituzionalismo.it,* 1/2021; P. Caretti, The *Constitutional Court closes the 'Cappato' case but stresses the need for legislative intervention on 'end-of-life' issues, in Osservatorio sulle fonti,* 1/2020; M. D'Amico, *'End of life' before the Constitutional Court between procedural issues and ethical dilemmas (Considerations on the sidelines of judgment no. 242 of 2019),* in *Osservatorio costituzionale,* 1/2020; R. Romboli, *The Constitutional Court decides on the 'Cappato case' and overcomes the insurmountable by approving the regulation of assisted dying,* in *Foro italiano,* 3/2020; A. Morrone, *The case and its law. Notes on the Cappato/Dj Fabo case,* in *Famiglia e Diritto,* 3/2020; A. Simoncini – C. Di Costanzo, *The contribution of the Constitutional Court to the development of biolaw,* in *BioLaw Journal – Rivista di Biodiritto,* 2/2019;

[38] Constitutional Court, order no. 207 of 2018, paras. 5-7 cons. in law;

[39] Among the hypotheses of jurisprudential formulation in the presence of which conduct abstractly attributable to the provisions of Article 580 of the Criminal Code is not punishable are: a) the irreversibility of the pathology; b) the presence of severe physical or psychological suffering that is absolutely intolerable; c) the indispensability of medical treatment aimed at sustaining the patient's life; thus, Constitutional Court ruling no. 242 of 2019; on the Court's decision-making technique, see M. Ruotolo, *The evolution of the Constitutional Court's decision-making techniques in incidental proceedings. For a framework for order no. 207 of 2018 in a new jurisprudential context,* in *Rivista AIC,* 2/2021; A. Ruggeri, *The regulation of assisted suicide is 'law' (or rather, 'judgment-law'), the result of the free invention of the Council, in the margin of Constitutional Court No. 242 of 2019,* in *Quaderni di diritto e politica ecclesiastica,* 3/2019; R. Romboli, *The 'Cappato case': a declaration of unconstitutionality that is 'taken, suspended and conditional', with some reflections on the future of the case,* in *Il Foro italiano,* 6/2019;

fundamental and conflicting rights, but the state's failure to abstain in such cases seems to lie in the unavailability of assets that may be relevant in certain cases, including, primarily, individual life, but also psycho-physical integrity.

The negative, or defensive, dimension of the right to health as a fundamental right does not fully exhaust its scope.

As highlighted in the previous pages, the very recognition of a 'fundamental right' implies a dual version of the same subjective situation, implying a dual attitude on the part of the recipient to whom it is addressed[40]: if, in order to ensure the negative dimension of the right, the State has an obligation to refrain from interfering in the sphere of individual freedom, on the other hand, there is a positive duty of intervention on the part of state institutions so that the protection of the right can be said to be effective, to the extent that such effectiveness is potentially prejudiced by the concrete conditions (social, economic, and cultural) in which the individual lives his or her life[41].

3.2 The right to health as a financially conditioned right

In order to attempt to provide a more complete analysis of the different legal situations covered by the constitutional provision of Article 32, it is necessary to dwell, albeit briefly, on the peculiar connotation that the right to health, understood in its dimension as a social right, has in relation to the receipt of healthcare services. On this point, it is important to start from the assumption, supported by part of the doctrine, according to the possible - further - subdivision within the scope of the provision in question. Based on this theory, it is considered possible to identify, within the text of Article 32 of the Constitution, a subjective dimension inherent in the fundamental individual right to health (which includes the positive dimension of freedom of choice in treatment and the negative dimension discussed in the

[40] F. Gallarati, *Constitutional obligations of protection: a comparative study on the 'forgotten' side of fundamental rights,* in *Rivista AIC,* 2/2024; A. Di Martino, *The dual dimension of fundamental rights,* in *Rivista del Gruppo di Pisa,* 1/2016; A. Celotto, *Rights (constitutional law),* in *Dig. Disc. Pubb.,* UTET, 2017, 278 ff.; F. Politi, *Constitutional freedoms and fundamental rights,* Turin, Giappichelli, 2021;

[41] on so-called performance rights, see R. Alexy, *Theory of fundamental rights,* Mulino, 2012;

following paragraph) and a social dimension in which the right to health is identified as the right to treatment[42] .

This second connotation finds a precise point of reference in the Constitution itself, in the part where it states, again in Article 32 of the Constitution, that "The Republic (...) guarantees free medical care to the indigent"[43] , which is confirmed in the rulings of the Constitutional Court[44].

The social dimension of the right to health, understood in its meaning as the right to receive healthcare services, to be more precise, appears to be a so-called conditional social right[45] insofar as it requires *interpositio legis* in order to give

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[42] On this point, see F.G. Cuttaia, *The recovery of the centrality of the right to health,* Giappichelli; L. Busatta, *Sustainable health. The complex determination of the right to access healthcare services,* Gippichelli Editore, 2018; Some authors have traced the structuring of the right to health back to the metaphor of Janus (in particular A. Vignudellli, *Il rapporto di consumo – profili di rilievo costituzionale [The consumer relationship – profiles of constitutional relevance],* Maggioli, 1984) to indicate how, in substance, a subjective right and a legitimate interest derive from it. "A varied and complex positive category, requiring (perhaps) a *continuous process* of interpretative updating in relation to needs, expectations (and the fragility and weaknesses typical of complex societies in advanced capitalism, a sort of Janus in which individual demands and claims, on the one hand, and objectively relevant collective values and expectations, on the other, manifest themselves and coexist in a relationship of integration and mutual osmosis," according to R. Ferrara, Il diritto alla salute: i principi costituzionali (The Right to Health: Constitutional Principles), in S. Rodi, Il diritto alla salute: i principi costituzionali (The Right to Health: Constitutional Principles), in S. Rodi, Il diritto alla salute: i principi costituzionali (The Right to Health: Constitutional Principles), in S. Rodi, Il diritto alla salute: i principi costituzionali (The Right to Health: Constitutional Principles), in S. Rodi individual demands and claims on the one hand, and objectively relevant values and expectations on the collective level on the other," according to R. Ferrara, *Il diritto alla salute: i principi costituzionali (The Right to Health: Constitutional Principles),* in S. Rodotà and P. Zatti (eds.), *Trattato di biodiritto (Treatise on Bio-law)*, Giuffrè, 2010.

Within these two profiles, it is possible to identify, according to some (R. Balduzzi – D. Servetti, *The constitutional guarantee of the right to health and its implementation in the National Health Service*, in R. Balduzzi – D. Servetti (eds.), *Manuale di diritto sanitario,* Bologna, Il Mulino, 2013) "five coordinated subjective legal situations: the right of the individual to have their health protected by the Republic; the general interest in the Republic protecting collective health; the right of persons in a state of poverty to claim free treatment; the freedom of the individual not to undergo or to refuse compulsory health treatment; the duty of the individual to undergo health treatments based on a legal obligation, never in violation of the limits imposed by respect for the human person."

[43] This guarantee of service provision only became effective in 1978 when the National Health Service was established by Law No. 833 of the same year; see § 4 below;

[44] Reference is made in particular to judgment No. 37 of January 31, 1991, in which the Constitutional Court established that the right to health "has the value of a social right, characterizing the form of the welfare state outlined by the Constitution";

[45] In the field of social rights, it is possible to distinguish between so-called original (or direct) social rights, which relate to relationships that can be freely activated by their holders, who can directly assert their (legally recognized) claims against the other party; from so-called derivative (or indirect) social rights, which require legislative intervention to establish the procedures for providing the services that constitute their content; on this point, see F. Modugno, *Lineamenti di diritto pubblico,* Turin, Giappichelli, 2010.

effect to this right[46]. The task entrusted to the legislator to implement the right does not correspond to the recognition of unlimited discretion on this point, as the latter is bound by the *Constitution,* limiting its margin of intervention only to the choice of the actual methods through which to provide healthcare services[47].

It is precisely in the context of establishing the methods by which the right to access healthcare services can be realized that the legislator is faced with the need to balance different factors, including the need to set limits on healthcare spending.

The economic conditions that characterize the right to healthcare services have been the subject of complex case law, in which the Constitutional Court has taken on the task of verifying the legitimacy of the balance struck in legislation. Starting from the recognition of the financial conditionality of the right to health, the Court itself has initiated a jurisprudential process aimed at modulating this conditionality, making it compatible not only with the fundamental nature attributed to health, but also adapting it to the entire fabric of constitutional values[48]. [49]It can therefore be said that, according to the approach developed during the 1990s, the *amount* of services required to ensure the development of the individual in relation to a certain type of social right must inevitably be considered in the light

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[46] On this point, A. D'Atena observes that social rights require implementing regulations, and that the provisions contained in the Constitution must be understood as 'preliminary provisions, not only dependent - in terms of their practical effectiveness - on the implementing and enforcement regulations, but also open to balancing operations by the constitutional courts'; A. D'Atena, *Constitutionalism and the Protection of Fundamental Rights,* in *Lessons in Constitutional Law,* Turin, Giappichelli, 2012;

[47] D. Morana, *Health as a Constitutional Right,* Turin, Giappichelli, 2013.

[48] In this sense, Constitutional Court ruling no. 304 of July 6, 1990 defines the social right to health as a financially conditioned right, guaranteed to every person as "a constitutional right conditional upon its implementation by the ordinary legislator through the balancing of the interest protected by that right with other constitutionally protected interests, taking into account the objective limits that the legislator encounters in its implementation, in relation to the organizational and financial resources available to it at the time."

[49] The line of case law relating to the so-called cost of rights stems from ruling no. 455 of 1990, whose constitutionality referred to a regulation of the Autonomous Province of Trento on healthcare services available to non-self-sufficient elderly people; the Provincial Council had in fact set spending limits for the use of certain services, and this provision had become the subject of the question raised before the Court. In declaring the question unfounded, the ruling focuses on the nature of the right to receive healthcare services as a right "subject to the determination of the instruments, timing, and methods of implementation of the relevant protection by the ordinary legislator and is configured as a right to positive benefits, based on constitutional provisions of a programmatic nature imposing a specific goal to be achieved"; para. 3, judgment no. 445/1990; on the ruling, see C. Salazar, *Economic crisis and fundamental rights – Report to the 28th AIC Conference*.

of a balance struck with other rights of equal constitutional importance but also with the limited resources available.

Although the Court was the first to recognize this inherent need for balance, intrinsic to the rights to benefits, in the course of its jurisprudential development it has been concerned with identifying the limits to this balance in order to prevent a fundamental right from being overwhelmed by financial needs.

Particular reference is made to the important ruling of 1994 no. 304, in which the judges of the Court identified the 'essential core of the right to health connected with the inviolable dignity of the human person' as the limit of protection that must necessarily be removed from the necessary balance with financial needs, in relation to which this dimension of the right to health cannot be compromised. The concept of the 'essential core of the right connected to human dignity' has been repeatedly affirmed by the Court in rulings aimed at reviewing the legitimacy of cuts or mechanisms aimed at reducing public spending on healthcare. Although difficult to define, its content has been gradually affirmed in case law[50] .

This concept seems to find its regulatory translation in the Essential Levels of Care[51], identified by the legislator as the level of protection that cannot be compromised[52] and therefore removed from the balance with other rights and

[50] In a 1999 ruling no. 309, concerning the transnational protection of the right to health, an initial definition of the "irreducible core of the right to health" is made to coincide with situations of economic hardship experienced by citizens, as a result of which the limitation of access to healthcare would represent an experience that the Court attributes to the limitation of human dignity. This ruling was followed by ruling no. 509 of 2000, in which, expanding the concept of 'irreducible core', the judges of the Court affirmed the need to 'prevent the creation of situations without protection that could prejudice the implementation of that right' (para. 4 cons. in law).

[51] *infra* Chapter III; enshrined at constitutional level as the exclusive competence of the State in the division of powers between the State and the regions pursuant to letter m), paragraph II, Article 117 of the Constitution, they are defined as "a clause guaranteeing a dynamic but balanced relationship between the unifying value of rights connected with national citizenship and demands for differentiation coming from territorial autonomies by establishing a minimum common standard for the protection of fundamental rights of a performance nature" according to G. Comazzetto, I *Livelli essenziali delle prestazioni tra processi di differenziazione e garanzie di uguaglianza (Essential Levels of Performance between Processes of Differentiation and Guarantees of Equality),* Jovene editore, Naples, 2024, p. 26.; M. Luciani, *Constitutional rights between the State and the regions (with regard to Article 117, paragraph 2, letter m) of the Constitution,* in *Politica del diritto,* 3, 2002; A. D'Aloia, *Rights and the autonomous State. The model of Essential Levels of Performance,* in E. Bettinelli, F. Rigano (eds.), *The Reform of Title V and constitutional jurisprudence. Proceedings of the seminar held in Pavia on June 6-7, 2003,* Giappichelli publisher, Turin, 2004; C. Pinelli, *Essential Levels of Performance, Fiscal Federalism Put to the Test of Delegated Decrees. 57th Conference on Administrative Studies,* Varenna, September 22-24, 2011.

[52] "Once the minimum guarantees necessary to make the right effective have been identified in law, it cannot be conditioned in absolute and general terms, (...) it is the guarantee of inalienable rights

needs[53]. Furthermore, as will be explained in more detail below, the Essential Levels of Performance (which, in the healthcare context, are referred to as Essential Levels of Care) also respond to the additional need to strike a balance between regional demands for autonomy and those for equality and uniformity in the protection of fundamental rights.

In determining the Essential Levels, first at the regulatory level through the Lea and, following the 2001 reform, with the Lep, it is possible to note a recovery of the role of the state legislator in the face of a healthcare system that finds its main cornerstone in the individual regional territories. This intervention by the central state is justified by the traditional role reserved exclusively for the national legislator as the sole entity responsible for protecting citizens' rights. [54]

In this context, there is a wealth of case law which, starting from the definition of the so-called irreducible core, establishes the impossibility of placing limits on the services included in the essential levels, thus conferring on them the intrinsic value of 'irreducible core of the right'[55] .

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that affects the budget, and not the balance of the budget that conditions their proper provision," according to Constitutional Court ruling no. 275 of 2016; on this point, see also Constitutional Court ruling no. 142 of 2021; "public finance requirements cannot, in the legislator's balancing act, take on such a preponderant weight as to compress the irreducible core of the right to health protected by the Constitution as an inviolable sphere of human dignity," ruling 309 of 1999 Constitutional Court; in the same vein, see also judgments nos. 267/1998; 416/1995; 304/1994; 247/1992 C. cost

[53] Recently the subject of a ruling by the Constitutional Court, No. 192 of 2024, in which the Court, in its judgment on the legitimacy of Law No. 86 of 2024 containing provisions for the implementation of differentiated autonomy, conceptually differentiated between Essential Levels and the Minimum Content of the right. while the latter is a limit deriving from the constitutional text, the protection of which cannot be financially conditioned, the Essential Levels are the result of a balance, an expression of the political choice from which their determination derives, 'a constraint for the legislator, taking into account the available resources'; see Judgment no. 192/2024 C. cost., cons. in law point 13.2

[54] The margin for intervention by the central government can also be found in other situations where the balance between financial needs and the management of the healthcare system is evident. Particular reference is made here to the system of healthcare recovery plans. This is a complex mechanism in which the pre-eminence of the role of the central government is confirmed through innovative methods such as the provision of substitute powers and the possibility of appointing commissioners ad acta in the financial management of the regional healthcare system involved.

[55] "Without prejudice to the political discretion of the legislator in determining - according to reasonable standards - the essential levels, once these have been correctly identified, it is not possible to limit their provision in practice through undifferentiated reductions in public spending" (judgment no. In such cases, situations would arise in which there would be no protection in all cases of failure to provide essential services, since the effectiveness of the right to obtain them can only derive from the certainty of the availability of the resources allocated to finance the satisfaction of that right,".

3.3 *Health protection: subjective right and collective interest*

Although the prescriptive nature of the rule in question is now no longer disputed by legal scholars, this connotation does not exhaust the plurality of legal situations arising from the provisions of Article 32 of the Constitution. As previously emphasized, the right to health is not qualified exclusively as a "fundamental right of the individual," but is also defined as a 'collective interest', with the direct consequence that the recipients of the regulatory provision are not limited to state institutions but also appear to include private individuals, who have a duty to refrain from any behavior that could potentially harm the health of others[56].

Therefore, considering health as an exclusively individual asset, placing the exercise of its protection in a dynamic that is fulfilled in relations between private individuals[57], it is possible to identify two levels of guarantee: a negative or passive guarantee, which results in the requirement that third parties refrain from any behavior that is harmful to the protected asset, providing for this purpose - pursuant to Article 24 of the Constitution, the instrument of judicial protection of subjective rights, accompanied by compensation where the undue intrusion of third parties in the exercise of the right has given rise to unjust damage[58].

In the face of such extensive individual protection, which is achieved through individual claims directed both at the institutional apparatus and at private individuals, the explicit qualification of health as a 'collective interest' allows limits to be placed on the enjoyment of this right.

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[56] Pezzini, *The right to health: constitutional aspects,* in *Law and Society,* 1983;

[57] Judgment no. 88 of July 26, 1979, Constitutional Court, on this point A. Anzon, *The other side of the right to health,* in *Constitutional jurisprudence,* 1979, p. 656 ff..

[58] The Supreme Court of Cassation itself has recognized the independent compensability of damage to health, following the recognition of the legal situation referred to in Article 32 of the Constitution as a "primary and absolute" subjective right, fully applicable in private relationships and with the consequence that any event causing damage to a person is relevant not only as an event detrimental to that person's ability to earn an income, but also independently (and in the absence) of this, as an unfailing impairment of that asset susceptible to independent assessment, which is psychological and physical integrity" Cass., Sec. III civ., May 11, 1989, no. 2150; "For an unlawful act that damages the psychological and physical integrity of a person, the compensable financial damage is not limited to the consequences for work and income-earning capacity, but extends to all negative effects on the primary asset of health, considered in itself as an inviolable human right"; Cass. Section III Civil, judgment no. 1130 of February 11, 1985.

Healthcare self-determination finds its insurmountable limit in the collective dimension of health protection, a limit that is justified in two ways. On the one hand, the limit to the individual's self-determination in healthcare is based on the essential premise that qualifies the good of life as a "precondition" for the enjoyment of all rights, as a supra-individual interest[59] ; on the other hand, this limitation is considered justified on the basis of its inseparable connection with the principle of solidarity[60] . This refers to the bidirectionality of the solidarity limitation deriving from the provision of the second paragraph of Article 32 of the Constitution, which operates both in relation to the protection of the individual, insofar as it prevents excessive freedom from leading a person to the deterioration of their health, and for the benefit of the community[61] .

What is most important, in fact, is the limit placed on the negative interpretation of the right – the so-called freedom not to be treated – which is considered secondary to the overriding collective interest[62] . It is precisely in this context that the regulations on compulsory vaccination[63] and compulsory health treatments (TSO)

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[59] The "fundamental good of life (...) is the first of the inviolable human rights recognized by Article 2 of the Constitution"; thus Constitutional Court judgment no. 223 of June 27, 1996; on this subject, see also O. Spataro, *Law no. 219 of 2017 and the regulation of end-of-life issues between constitutional principles and unresolved problems. Food for thought,* in *Riv. BioDiritto,* 2019,2.

[60] A more traditionalist approach translates this conflict between self-determination and collective interest in healthcare into the famous tension between 'the power of the individual over themselves and their own body and the authoritative intervention of the public decision-maker in matters of the right to health'; however, according to a more modern doctrine, it is considered preferable not so much to frame the issue in such absolutist and anachronistic terms, but rather to consider this conflictual situation as attributable to the relationship between the personalistic principle and the solidarity principle, proposing an interpretation more in line with the values and principles of modern constitutionalism, of which the Italian Constitution is the spokesperson; Thus, M. Nocelli, *Authority and freedom in healthcare decisions between the principle of solidarity and the principle of individual rights,* in www.giustizia-amministrativa.it;

[61] "The principle of solidarity, as it is applied in relation to the constitutional guarantee of health, essentially consists of a rule of balance between the multiple legal positions that the complex case of Article 32 of the Constitution aims to safeguard," according to D. Morana, *Principle of Solidarity, Right to Health, and Vaccination Obligations,* in *Comparative Rights,* 2024.

[62]M. Cartabia, *Constitutional jurisprudence relating to the second paragraph of Article 32 of the Constitution*, in *Quad. Cost.*, 2012; M. Nocelli, *Authority and freedom in healthcare decisions between the principle of solidarity and the principle of personalism,* cit.; V. Gastaldo, *Compulsory healthcare treatments and the constitution*, in *Riv. BioDiritto*, 2019, 2.

[63] The issue of compulsory vaccinations has long been the subject of debate along two lines: on the one hand, the decision to introduce compulsory vaccinations through state law has been contested on the grounds of excessive restriction of individual freedom; on the other hand, such legislative measures have led the regions on several occasions to complain of excessive interference in their spheres of competence. A wealth of constitutional case law has developed on the subject, aimed at curbing these arguments and establishing the conditions and instruments through which the imposition of vaccinations at the legislative level can be considered legitimate. In particular, reference is made to judgments nos. 307 of 1990; 5 of 2018; 14 of 2023; 15 of 2023; 25 of 2023.

find their raison d'être, given that these are the two cases in which the conflict between the individual dimension – understood in the sense of freedom of self-determination – and the collective dimension[64] emerges with particular vehemence. Although the provision of a limit on freedom of self-determination may echo a paternalistic narrative, conflicting with current constitutional dynamics, in reality it seems possible to identify in the tension between individual rights and collective interests inherent in the right to health, an emblematic search for balance between two fundamental principles of the Italian constitutional order: the personalistic principle and the solidarity principle.

4. *The implementation of Article 32 of the Constitution: the National Health System*

The law establishing the National Health System, dated 1978 no. 833, is perfectly in line with the founding ideology of the constitutional provision referred to in Article 32 of the Constitution. Although the assertion regarding the prescriptive nature of the provision was far from unanimous in the years following the entry into force of the Constitution[65] , the adoption of Law No. 833 of 1978 [66] is perfectly

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Based on the consistent jurisprudential orientation that has developed on the subject, it is now possible to affirm that, for a law introducing mandatory vaccinations to be legitimate, certain conditions must be met, such as: The imposed medical treatment must be aimed at improving not only the health of those subjected to it, but also at preserving the health of others. it must not adversely affect the health of those subjected to it, except for those consequences that appear normal and therefore tolerable; fair compensation must necessarily be provided for the injured party in addition to parallel compensation protection. Furthermore, Constitutional Court ruling no. 25 of 2023 highlights the particular need for the legislator to identify with the necessary certainty in the relevant law the specific medical treatment to which individuals are to be subjected in order to satisfy the legal requirement set out in the second paragraph of Article 32 of the Constitution.

[64] Constitutional Court Ruling No. 268 of December 14, 2017, *"With regard to vaccination treatments, the technique of compulsory vaccination (...) is not incompatible with Article 32 of the Constitution if the compulsory treatment is aimed not only at improving or preserving the health of those subjected to it, but also that of others, since it is precisely this additional purpose, relating to health as a matter of public interest, that justifies the restriction of the individual's self-determination."*

[65] On this point, see R. Ferrara, I *principi,* in *Salute e Sanità,* in S: Rodotà, P. Zatti (eds.), *Trattato di biodiritto,* Giuffrè editore, 2010;

[66] The National Health Service is defined in the third paragraph of Article 1 of Law No. 833 of 1978 as "a set of functions, structures, services, and activities intended to promote, maintain, and restore the physical and mental health of the entire population without distinction of individual or social

consistent with the content of the constitutional provision it aims to implement. Contributing to this was the lively doctrinal debate against the recognition of equal dignity of social rights-benefits compared to the more traditional rights of freedom. For a long time, the right to health—understood as the first among social rights—was considered *inferior* to traditional freedoms[67] . Today, the recognition of the right to health as a fundamental prerogative for the enjoyment of all other rights contemplated or contemplatable – in accordance with the so-called open clause of Article 2 – is indeed undisputed and uncontestable.

Preceded by the first healthcare reform of 1968[68] – Law No. 132 of 1968 – the 1978 law builds on its foundations, developing a healthcare system based on the principles of equity, universality, and equality. on the basis of which the organizational principles are articulated, consisting of: the centrality of the person, collaboration between different levels of government, enhancement of the professionalism of healthcare operators, and social and healthcare integration.
There are two main merits of the 1978 legislation. On the one hand, the law in question had the great merit of establishing a free National Health Service accessible to all, constituting an important step forward from the previous mutualistic system, which 'had been a benefit reserved for employed workers, with different services for different economic sectors and professional categories, conditional on the payment of different fees proportionate to the services provided'[69] . The principles of comprehensiveness and universality, which underpin the entire system, are those that most closely comply with the constitutional

conditions and in accordance with procedures that ensure equality of citizens with regard to the service."

[67] C. Bottari, *Il diritto alla tutela della salute (The Right to Health Protection*), cited above, defines the right referred to in Article 32 of the Constitution as an "exponential corollary to the protection of freedom, or rather the other side of freedom, for the recognition and guarantee of which declarative proposals in general are useless and, in many ways, even superfluous."

[68] Known as the Mariotti Law, named after the then Minister of Health Luigi Mariotti, thanks to which the voluntary and charitable welfare system was replaced, establishing hospitals as public entities subject to state management and control; pursuant to Article 1 of Law No. 132 of 1968, "Public hospital care is provided to all Italian and foreign citizens exclusively by hospital entities" defined, pursuant to Article 2 of the same law, as "public entities that institutionally provide for the hospitalization and care of the sick."

[69] Thus F. Taroni, *Healthcare and regions in a national health service,* in M. Salvati, L. Sciolla, *Italy and its regions. The Republican era,* vol. I, Treccani Encyclopedia Institute, 411 ff.

provisions of Article 32 of the Constitution, in relation to which the National Health Service acts as an implementing instrument[70] .

On the other hand, the system outlined is part of a regional system whose contours were uncertain and blurred at the time.

The 1978 legislation provided for a system based on local health units, under the jurisdiction of municipalities, as health protection was considered a purely local interest, and on a network of hospitals as public bodies with legal personality. the regional authority was assigned a planning and control function at the territorial level, while the central government was responsible for national health planning, which was carried out by determining the standardized health needs of the population, on the basis of which the financing of the National Health Service was arranged. This system was complemented by the possibility of participation by entities outside the healthcare system[71] , in accordance with what can now be traced back to the principle of subsidiarity[72] .

The financing of the National Health Service, consisting entirely of citizens' contributions to public finances, quickly entered into crisis due to its inability to cover all the costs associated with the organization of facilities and the services provided.

The main critical issue identified in this mechanism was attributed to the fiscal hetero-direction of the system, meaning the dissociation between those responsible for determining expenditure and those responsible for collection: the government, through the budget, was responsible for annual financial planning, in which the amount of resources reserved for the health sector was identified and then distributed among the various regions. This had two consequences. Firstly, this system contributed to worsening the deficit in the public coffers, creating a total

[70] "The Republic protects health as a fundamental right of the individual and in the interest of the community through the national health service," Art. 1 Law No. 833/1978.

[71] This possibility, now attributed to the principle of subsidiarity understood in a horizontal sense, was originally attributed to what is defined as "the most direct realization of the principle of social solidarity, whereby the individual is called upon to act not out of utilitarian calculation or under the imposition of an authority, but as a free and spontaneous expression of the profound social nature that characterizes the individual himself," according to C. Bottari, *The right to health protection,* cit.

[72] Art. 1, paragraph 5, Law No. 833 of 1978: 'Voluntary associations may contribute to the institutional aims of the national health service in the manner and forms established by this law'.

lack of accountability among those responsible for spending. Secondly, the way the system worked restricted the autonomy that the regions had at the time[73] .

The public finance *deficit* in the healthcare sector led to a period of reforms starting in the 1990s, implemented by Legislative Decree No. 502 of 1992 and the subsequent Legislative Decree No. 229/1999.

Three guidelines can be identified through which these reforms have moved, with the ultimate goal of rebalancing the healthcare budget *deficit*. The national legislature has intervened to reduce healthcare spending by i) by granting greater decision-making autonomy to the regions in the healthcare sector and thus shifting the Local Health Authorities (USL) from municipal management to regional control, ii) by granting broader organizational powers to the regions, which were then responsible for covering any expenses exceeding the amount allocated at the state level; and, finally, iii) by redefining hospitals in a private sense, i.e., identifying these entities as companies[74] .

This regionalization and corporatization, according to some, excessively undermined the principles that inspired the 1978 reform, particularly fairness and equality, giving rise to a dualistic system that favored the wealthiest individuals and the most productive areas. The process of regional differentiation, which subsequently resulted in twenty-one regional health services[75] , is traced back to the period immediately following the reforms of 1992 and 1993, identified as a

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[73] "Institutional relations between the state and the regions were therefore mainly expressed in the budgetary policies drawn up unilaterally by the central government through annual finance laws, which ended up significantly reducing the powers of the regions through a process of recentralization justified by the need to control public spending," according to F. Taroni, *Sanità e regioni in un servizio sanitario nazionale (Healthcare and regions in a national health service),* op. cit.; on this point, see also E. Buglione, G. France, *Skewed fiscal federalism in Italy: implications for public expenditure control,* in *Public budgeting & finance,* 3, 1983.

[74] Particularly noteworthy is the provision in Article 9 of Legislative Decree 502 of 1992 entitled 'Differentiated forms of assistance', which allows citizens to turn to private healthcare facilities, giving rise to a system known as the 'double pillar' in which the universal public model determined by the National Health Service is accompanied by private facilities providing healthcare services only for 'the rest of the population', as stated by M. Cosulich, *Equità va cercando... the National Health Service, an instrument for the implementation of Article 32 of the Constitution,* in *Corti Supreme e salute,* 1, 2022. This provision was amended by Legislative Decree 517 of 1993, which replaced the classification of forms of assistance, no longer differentiated but complementary, thus providing for 'the possibility of establishing supplementary funds aimed at providing additional services' on point B. Pezzini, *The 1992 reorganization (a universal healthcare system, despite the 1992 reorganization),* in *Supreme Courts and Health,* 3, 2018.

[75] F. Taroni, *Healthcare and regions in a national health service,* op. cit.

consequence of poorly defined legislation and a continuous succession of short-lived governments.

In order to ensure the legitimacy of cuts to public funding for healthcare expenditure and to bring regionalization back within the unified framework of the National Health System[76] , the 1999 legislature[77] established Essential Levels of Care, , which are determined by law through the National Health Plan[78] and guaranteed uniformly throughout the country.

From the outset, the Lea have been oriented towards a dual purpose: on the one hand, they responded to the need to curb cuts in healthcare, constituting the limit against which the state's interest in balancing the budget could not be considered paramount; on the other hand, they constitute a uniform measure for the protection of a fundamental right within a regional state in which, in the healthcare sector, following the reforms carried out in the 1990s, regional authorities are assuming an increasingly important role[79] . In particular, this instrument has been used to attempt to objectify the measurement of the 'essential' healthcare needs of the population[80]

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[76] Establishing the coexistence of the national and regional character of the National Health Service, the latter is defined as 'the set of functions and care activities of the regional health services', Art. 1, para. 1 of Legislative Decree 229 of 1999.

[77] The change in name from 'Uniform Levels of Care' (former Legislative Decree 502 of 1992) to 'Essential Levels of Care' is emblematic; a transition that acquires an ultra-semantic value given that, while in the 1992 legislation the levels were considered "minimum" and therefore conditioned by the provider's financing capacity, with the 1999 reform, the LEA definitively acquired autonomy and were removed from the balance sheet constraints; See M. Cosulich, *Equità va cercando… il Servizio sanitario nazionale, strumento di attuazione dell'art. 32 Cost. (Equity sought... the National Health Service, instrument for the implementation of Article 32 of the Constitution*), cited above; R. Balduzzi, *Livelli essenziali e risorse disponibili: un nodo costituzionale? (Essential levels and available resources: a constitutional issue?),* in *Scritti in onore di Angelo Mattioni (Writings in honor of Angelo Mattioni)*, Milan, 2011.

[78] The National Health Plan, which is responsible for determining the LEA, following the amendment made by Legislative Decree 502 of 1992, is established by government decree, subject to agreement with the Permanent Conference of States, Regions, and Autonomous Provinces, after a partially binding opinion from the relevant parliamentary committees.

[79] In line with the reforms implemented, the healthcare system is divided into three different levels of government: "national in terms of guarantees of uniformity and universal access, regional in terms of planning, and municipal in terms of management," according to B. Pezzini, *Il riordino del 1992 (A universal healthcare system despite the 1992 reform),* op. cit.; in which the author attributes regionalization to an "accounting cosmetic operation" in that the strengthening of the regional role in healthcare responds to the need to conceal the cuts in healthcare spending made at the central level; on this point, see also A. Mattioni, *Le quattro riforme della sanità. A synoptic reading of fundamental institutional junctures,* in R. Balduzzi (ed.), *Thirty years of the National Health Service. An interdisciplinary comparison,* Mulino, Bologna, 2009; C. Bottari, *Health Protection and Healthcare Organization,* Giappichelli, Turin, 2009.

[80] "Economic and financial choices would be instrumental in guaranteeing an ideal quantity of healthcare services that every individual in the country should be able to receive in order to enjoy a state of psychological and physical well-being understood in an objective sense," according to E.

- which must necessarily be sustainable from a public finance point of view[81] - and, at the same time, put a stop to regionalization, preventing differences in performance between the various regional healthcare systems from negatively affecting the protection of health as a right to which all citizens are equally entitled, thus ensuring a minimum level of healthcare services that must be guaranteed uniformly throughout the country.

Following the reforms of the 1990s, seen by some as a symptom of the crisis of the 'material constitution' in the broad sense and of the welfare state in the strict sense[82] ; it is possible to continue to affirm the principles on which the first healthcare reform of 1978 was based – namely universality and equality – but in light of a series of corrective measures driven by the regionalist movement that culminated in our internal legal system with the constitutional reform of 2001[83] , following which it became necessary to redefine the institutional balance in order to maintain the guarantees that permeate the constitutional fabric in the area of the protection of fundamental rights, including the right to health[84].

5. *The new paradigm in health protection: the One Health approach*

The evolutionary process that led to the concept of 'health' as it is understood today has been marked in particular by the recent pandemic caused by the spread of the Covid-19 virus. The impact of the pandemic has not been limited to the purely

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Cavasino, *Why establishing the right to health as a 'right to service' makes regulatory forms of equality dependent on economic and financial constraints and reduces the guarantee effect of the 'minimum essential content',* in *Gruppo di Pisa,* 3, 2012.

[81] On this point, for a reconstruction of the system, see S. Spatola, *The usual dilemma: health financing between effective protection and budgetary requirements. Evolution, criticism, and prospects in light of the recent social debate,* in *Supreme Courts and Health,* 3, 2023; F.G. Cuttaia, *The financial conditioning of the social right to health: foundations and prospects for evolution, astrid-online, 9*, 2020; M Atripaldi, *The right to health and essential levels of care, federalismi.it,* 2017; L. Antonini, *Decision-making techniques and balancing rights and finances,* in F. Pammolli, C. Tucciarelli (eds.), *The cost of rights,* Bologna, 2021.

[82] Thus B. Pezzini, *The 1992 reorganization,* op.cit.

[83] On the territorial organization of health protection, following Constitutional Law 3/2001, see Chapter III

[84] R. Nania, *The right to health between implementation and sustainability,* op. cit. speaks in this regard of 'the degree of constitutional tolerability of the diversification that the treatment of the right in question could receive, in line with the autonomous structure of the legal system'.

organizational dimension, where it has revealed certain discrepancies concerning predetermined decision-making models. Rather, the legacy of this emergency context has led to a redefinition of the very concept of health as a fundamental and primary object of protection.

The One Health approach proposes an integrated and multidisciplinary vision of human, animal, and environmental health[85]; which, compared to the traditional concept of health as a state of physical and psychological well-being of human beings—from which the constitutional term originates—differs from and constitutes an evolutionary variation.

The holistic approach resulting from the adoption of One Health could indeed raise critical issues both from the point of view of the substantive protection of the right to health as enshrined in constitutional charters, but also from a purely organizational point of view.

From the first point of view, full adherence to the integrated approach to health protection required by One Health seems to originate from eco-centric theories of law[86] , which, anchored in philosophies that recognize the legal subjectivity of Nature, appear to conflict with the purely anthropocentric views on which the post-war European constitutions are based.

However, this conflict appears to be surmountable, insofar as even the Italian Constitution, while maintaining the principle of individual rights as its fundamental principle, cannot conflict with the implementation of strategies aimed at protecting social rights. It is also worth noting that the intertwining of human, environmental, and animal health is not a novelty deriving exclusively from the implementation of international guidelines; on the contrary, the Constitutional Court has often emphasized the polysemic nature of health protection as understood in the

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[85] The term One Health did not originate during the pandemic period; in fact, it derives from the so-called Manhattan Principles of 2004, which can be consulted on the website. The first of these, emblematic for the purposes of defining this approach, refers to the need to "Recognize the essential link between human, domestic animal, and wildlife health and the threat disease poses to people, their food supplies and economies, and the biodiversity essential to maintaining the healthy environments and functioning ecosystems we all require"; "Solving today's threats and tomorrow's problems cannot be accomplished with yesterday's approaches. We are in an era of One World, One Health, and we must devise adaptive, forward-looking, and multidisciplinary solutions to the challenges that undoubtedly lie ahead."

[86] Thus, in particular, G. Ragone, *One Health and the Italian Constitution, between ecocentric pressures and new perspectives on the protection of human, environmental, and animal health,* in *Corti Supreme e Salute,* 3, 2022.

constitutional text, thus bringing the threefold distinction—human, environmental, and animal health—into the protective framework of Article 32 of the Constitution, suggesting that the rigid division of subjects should be overcome even before the One Health approach entered our legal system.

Furthermore, following the constitutional reform implemented through Constitutional Law 1 of 2022[87] , all the elements that constitute the triad on which One Health is based are explicitly recognized at the constitutional level. Following the aforementioned reform, Article 9 of the Italian Constitution assigns the Republic the task of protecting 'the environment, biodiversity, and ecosystems', reserving to state law the task of regulating 'the methods and forms of animal protection'.

Although even after this reform it is not possible to identify the Italian Constitution as an eco-centric constitution, it has had the merit of crystallizing values relating to the protection of the environment, ecosystems, and animal h s within the framework of constitutional values. It also constitutes the concretization of giving the same importance to policies aimed at implementing the One Health approach.

From an organizational point of view, the reception given to the recommendations of international organizations, such as the World Health Organization, on the need to emphasize the indissoluble link between the protection of human health and the protection of the environment has led, first at the European level and then within individual national legal systems, to the preparation of plans to reform health systems in line with the One Health approach.

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[87] On the reform implemented by Constitutional Law 1/2022, see T.E. Frosini, *La Costituzione in senso ambientale, una critica (The Constitution in an environmental sense, a critique),* in *federalismi.*it, 2021; I. A. Nicotra, *The inclusion of the environment in the constitution, an important signal after* Covid, in *federalismi.*it, 2021; and F. Urso, *Environment, ecosystem, and biodiversity. Some reflections based on a constitutional revision project,* in *Annali – Università Suor Orsola Benincasa,* Vol. I, 2021, pp. 81 ff; M. Cecchetti, *The revision of Articles 9 and 41 of the Constitution and the constitutional value of the environment: between averted risks, some (also) innovative virtues, and many gaps,* in *Forum di Quaderni costituzionali Rassegna,* no. 3/2021, p. 305 ff.; E. Di Salvatore, *Brief observations on the revision of Articles 9 and 41 of the Constitution,* in *Costituzionalismo.it,* issue no. 1/2022; For a wide-ranging reflection on the role of the environment in the Constitution, see in particular S. Grassi, *Environment and Constitution,* in *Rivista quadrimestrale di diritto dell'ambiente,* no. 3/2017, pp. 4 ff. as well as B. Caravita, A. Morrone, *Environment and Constitution,* in B. Caravita, L. Cassetti, A. Morrone (eds.), *Environmental Law,* Bologna, 2016, pp. 17 ff.

This approach requires cross-sectoral coordination, involving various experts in the field, but also intergovernmental coordination, as it is part of the division of powers between the European Union, the central government, and local authorities. This objective requires, on the one hand, widespread action among the population through the intervention of local structures and, on the other, action at the national and supranational levels. [88]

The adoption of the integrated approach embodied by One Health poses pitfalls for the Italian national legal system for two reasons. Firstly, the intertwining of competences in the fields of health, environmental and animal protection, which, in light of the division of competences outlined in the Constitution, cannot be attributed to a single subject[89] .

Health protection and environmental protection fall within the division of powers between the State and the regions outlined in the Italian Constitution, as referred to in Article 117 of the Constitution, as separate areas of competence: with regard to health protection, this is a concurrent competence (in which only the State is responsible for determining the LEA), while environmental protection is defined as the exclusive competence of the State. Animal protection is not included among the competences referred to in Article 117, but, following the 2022 amendment, the new Article 9 of the Constitution refers to State law with regard to determining the methods and forms necessary for the implementation of such protection, implicitly recognizing the State's competence to regulate the matter.

The second critical issue follows on from the first and concerns the practical way in which this intertwining of competences is actually exercised in order to ensure, on the one hand, compliance with constitutional provisions and, on the other, to allow the introduction of innovations aimed at reforming the health system in such a way as to make the adoption of the new approach effective[90] .

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[88] See S. Iaria, *The potential of the NRP and the 'One Health' project in the context of revitalizing local healthcare,* in *Administration on the Way Forum,* 2024;

[89] see A. Saporito, *The National Recovery and Resilience Plan and the right to health, a new evolution?,* in *Amministrativ@mente,* 1/2024;

[90] See on this point M. Gnes, *The resilience of the Italian healthcare system and the COVID-19 emergency,* in *Global Pandemic Network,* December 2023, vol. 2; G. Ragone, *One Health and the Italian Constitution, between ecocentric pressures and new perspectives on the protection of human, environmental, and animal health,* in Corti Supreme e Salute 3/2022;

Following the adoption of Regulation EU/2021/244 establishing the Recovery Fund, the One Health approach was incorporated into European legislation[91] as a key principle that individual Member States, as part of their reform plans included in their respective National Recovery and Resilience Plans, had to follow in defining healthcare reforms.

As a result, at the national level, the need to set up a healthcare system capable of implementing European guidelines became positive law with the enactment of Decree Law No. 111 of 2021, which, within Mission No. 6 of the National Resilience Plan[92] , specifies the need to 'designate a new institutional framework for prevention in the areas of health, the environment, and climate'. This new institutional framework, as mentioned above, outlines the distribution of responsibilities which, in the field of health protection, involves the participation of various institutional actors.

Firstly, it should be noted that the healthcare reform, currently in preparation, consists of two actions: the definition of uniform structural, organizational, and technological standards for territorial care; accompanied by the definition of a new institutional framework for health, environmental, and climate prevention in line with the One-health approach.

This second action is implemented in the PNRR2 decree law (Law No. 79/2022)[93], which approves the following system. On the one hand, at the central level, the establishment of the National System for the Prevention of Environmental and Climate Risks (SNPS)[94], which identifies and assesses health issues associated with environmental and climate risks in order to contribute to the implementation of

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[91] The first legislative reference at European regulatory level is found in EU Reg.2021/522, which will be discussed in more detail in Chapter II, which defines the One Health approach precisely in Articles 3 and 4 as "a multisectoral approach that recognizes that human health is linked to animal health and the environment and that actions to address health threats must take these three dimensions into account.

[92] The reform of the healthcare system outlined in the Sixth Plan mission is in turn divided into two groups of objectives: Component 1: Neighborhood networks, facilities, and telemedicine for local healthcare; Component 2: Innovation, research, and digitization of the National Health System. Component 1, in turn, is divided into four lines of action: creation of community homes; the home as the primary place of care and telemedicine; community hospitals; health, environment, biodiversity, and climate.

[93] Art. 27, paragraph 2 of Decree-Law 79/2022, known as the PNRR2 Decree

[94] Pursuant to Art. 27, paragraph 4, Law No. 79/2022, the SNPS includes the prevention departments of the local health authorities and autonomous provinces, the Experimental Zooprophylactic Institutes, the Higher Institute of Health, and the Ministry of Health.

prevention policies ; contributes to the definition of Essential Levels of Care; and identifies an integrated monitoring system[95] with the National System for Environmental Protection (SNPA)[96] .
At the regional level, on the other hand, the Regional System for the Prevention of Environmental and Climate Risks (SRPS)[97] has been established, which contributes to the pursuit of the objectives set at the central level by adapting them to the specific characteristics of the territory in which it operates.
As a means of linking the two systems, the National Environmental Protection System is designed as a centralized control room that aims to better integrate the actions of the local system with those of the central system.
The Italian legislator therefore chose to replicate the scheme adopted at the central-state level at the local-regional level as well. The aim is to achieve the objectives set through the One Health approach, while ensuring the integration of local issues and therefore the inevitable involvement of local authorities in the implementation of the decree, while maintaining strict compliance with the constitutional principle of loyal cooperation on which the structure of relations between the different levels of government is based.

Although concrete evidence is still to be found, it can be said that through this organizational system, the Italian legal system has attempted to respond to EU requirements in the definition phase of the PNRR, and, in particular, it constitutes an attempt at a One Health approach, incorporating this method of protection into an institutional landscape characterized by a complexity of legislative actors.
On the other hand, from a purely substantive point of view, although this is an evolutionary perspective on health protection compared to that traditionally referred to in Article 32 of the Constitution, following the 2022 reform, the so-called triad that makes up the One Health approach – human health, animal health,

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[95] To this end, a Steering Committee has been set up within the Presidency of the Council of Ministers, composed of a representative of the Presidency of the Council of Ministers, two representatives of the SNPS, two representatives appointed by the Minister for Ecological Transition, and a representative of the regions and autonomous provinces appointed by the State-Regions Conference.
[96] Established by Law No. 132 of June 28, 2016.
[97] Choice made by decree of the Minister of Health of June 9, 2022, implementing the PNRR2 decree law.

and environmental protection – is expressly recognized, and consequently protected, within the Constitution.

CHAPTER II

HEALTH 'BEYOND' THE STATE: SUPRANATIONAL HEALTH PROTECTION

SUMMARY: 1. Health protection in the supranational context. - 2. Health protection policies in the European Union. – 2.1 Continued. Cross-border healthcare. – 2.2 Continued. Post-COVID policies: sign of a new awareness? - 3. Health protection in international law: the World Health Organization. – 3.1. Continued. The role of the WHO in managing health emergencies of international concern. – 3.2 Continued. The World Health Organization and the pandemic emergency: the new treaty. - 4. Concluding remarks: the impact of supranational legislation on the substantive and organizational dimensions of the right to health.

1. Health protection in the supranational context.

In order to carry out as comprehensive an analysis as possible of the dynamics relating to health protection, in its substantive and organizational dimensions, it seems essential to devote a specific study to its contextualization in supranational law, which, as regards the legal system under discussion, consists of an analysis of European Union regulations and those dedicated to it by the main international organization, namely the World Health Organization.

This contextualization is necessary, on the one hand, due to the effect of the transfer of sovereignty from national states to supranational organizations, which has led to a proliferation of decision-making bodies and, on the other hand, due to the extreme effects of globalization, which can be seen in every aspect of daily life. This scenario brings with it the need to redefine aspects relating to health protection by proposing an evolutionary interpretation of its traditional paradigms.

The path towards opening up to supranational legislation—or legislations—responds to the most current needs inherent in health protection which, in the current context, no longer seems to be confined to management strictly limited to the boundaries of each state.

The analysis of the supranational context of health protection can be explored in depth along three lines of inquiry.

Firstly, from a purely substantive point of view of the protection of rights, it is necessary to emphasize that the multitude of institutional scenarios has led to a quantitative increase in the protection itself ( ). In a regulatory context that distances itself from the absolute centrality of national parliaments, there are now multiple forums in which the substantive protection of fundamental rights is realized[98].

In this sense, legal theory has come to define today's regulatory and institutional landscape as multilevel constitutionalism, describing a context in which the protection of rights is achieved through an integrated reading of the various charters in which these rights are recognized.[99]

Secondly, it seems clear that even the organizational dimension of healthcare, traditionally reserved for national competence, can be influenced by the supranational regulatory context[100] in more or less direct ways. In fact, an increasing number of EU legislative initiatives appear to be capable of bringing

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[98] See on this subject M. Cartabia, *La tutela multilivello dei diritti fondamentali. Il cammino della giurisprudenza costituzionale italiana dopo l'entrata in vigore del Trattato di Lisbona (The multi-level protection of fundamental rights. The path of Italian constitutional jurisprudence after the entry into force of the Treaty of Lisbon),* Trilateral meeting between the Italian, Portuguese, and Spanish Constitutional Courts in Santiago de Compostela, October 16-18, 2014; A. Ruggeri, *Direct Effects of EU Rules and the Constitution,* in *Rivista AIC,* no. 2, 2015; A. Spadaro, *European Integration and Global Constitutionalism,* in *DPCEonline, no*. 2/2021, p. 2431 ff; the author refers to 'a surprising, innovative and more general phenomenon of integration between sources, based on the subsidiary replacement of one source by another, in derogation from both hierarchy and competence mechanisms'; for a more in-depth examination of this point, see R. Bin, *Critica alla teoria delle fonti,* FrancoAngeli, Milan, 2018;

[99] The European Union, as an international organization, is still making progress towards its full realization, moving within a complex process based on the gradual acquisition of powers by the Union, in exchange for a progressive transfer of sovereignty to the latter by the Member States. Within this evolutionary process, which is still ongoing, the protection of rights occupies a fundamental position in the creation of a common constitutional system. The enactment of the Charter of Nice in 2000 and its subsequent legalization with the Treaty of Lisbon in 2007 undoubtedly marked an important step forward in the construction of a European system for the protection of rights. In order to create a European constitutional system, each individual court must perform its role by drawing on the content of every constitutional charter in Europe with the ultimate aim of achieving the best possible protection, in accordance with Article 52 of the Charter of Nice. In the absence of a hierarchical order among the founding charters of rights, it is considered necessary that the latter "integrate and complement each other in their interpretation" (Constitutional Court ruling no. 388 of 1999).

[100] 'As a first point, it can therefore be said that there is a basic notion of the right to health that can be considered established, which transcends national borders and is represented by the treatment of diseases. Then there are the stages of prevention and the pursuit of individual well-being, which are instead left to the development of public policies on the subject, also because of the connection they often have with the ethical, cultural, and sometimes even religious values of a community," according to A. Papa, *La tutela multilivello della salute nello spazio europeo: opportunità o illusione (The multilevel protection of health in the European space: opportunity or illusion),* in www.federalismi.it, 4, 2018.

about changes in the functioning of the National Health Service, even indirectly[101]. The role attributed to the World Health Organization in the management of international health emergencies is also significant, as will be explained below. These contexts give rise to the attribution of important prerogatives to the Organization itself.

Finally, the study of the supranational regulatory context relating to the protection of the right to health is made necessary by the specific context in which this object of protection is situated. In a scenario in which the borders of national states are becoming 'porous'[102] in the face of the speed of exchange and movement of goods, people, and animals, the needs associated with health protection can no longer be met within the rigid boundaries of individual nations.

The global dimensions assumed by health therefore require the intervention of a regulatory system capable of reflecting those dimensions.

Given the particular constitutional importance of the European Union in the internal legal system, it is considered necessary to start from an analysis of the legislation adopted by the EU.

Despite the explicit recognition of the right to health in the Charter of Nice[103] ; in the context of the division of powers between the Union and the Member

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[101] Particular reference is made here to the 'strong influence exerted by European policies, which in the past have been more attentive to market values and competition and less sensitive to overcoming inequalities', according to L. Chieffi, *Equità nella salute e nei servizi sanitari tra politiche europee e interventi statali (Equity in health and health services between European policies and state interventions),* in *Corti Supreme e Salute,* 1, 2022; in which the author traces the austerity policy leading to the Stability Pact and the ban on excessive public deficits in the years following the 2008 economic crisis, which had the effect of forcing Member States to contain public spending, thereby also reducing the investments necessary to protect social rights; on this point, see also C. Colapietro, *Social Rights Beyond the State. il caso dell'assistenza sanitaria transfrontaliera (Social rights beyond the state. The case of cross-border healthcare),* in *costituzionalismo.it,* 2, 2018.

[102] "There is a growing number of rules, administrative procedures, bureaucracies, and judgments in the global space, dictated and established to set common rules for global markets, promote and protect universal rights, safeguard public goods of global value, and ensure the effectiveness of supranational legal orders," according to S. Cassese, *Stato in trasformazione (The State in Transformation),* in *Riv. Trim. Diritto pubblico,* 2, 2016; in which the author speaks of the "historicity of the state phenomenon" referring to the need to "re-conceptualize the state in the context of the new trends and transformations that have emerged: internal changes, resulting from shifting borders and the redefinition of the state's personnel base (...) and external changes, resulting from the integration of the state into higher functional units, where shared sovereignty is exercised."

[103] Thus, Article 35 of the Charter of Fundamental Rights of the EU, entitled "Health protection," states that "Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities."

States, health protection is identified as a matter of purely national interest. The European Union appears to have a submissive attitude towards the protection of fundamental rights in general, and in particular with regard to health protection. It continues to take an approach aimed at coordinating the various national policies on the subject.

This is certainly still a work in progress, which recently seems to show trends that are partially at odds with the traditional attitude of distance on the part of European institutions. The importance of this sensitive sector—whose impact at the supranational level has recently been confirmed by the Covid-19 pandemic—has led the EU itself to take steps toward the creation of what, although still in the hope phase, seems to be called the European healthcare system. This goal does not seem so far off, following the legislative initiative that led to the adoption of Directive 2011/24/EU on cross-border healthcare.

While the EU is grappling with a renewed awareness of the supranational importance of health protection, the European Convention on Human Rights remains silent on the issue, with no provisions reserved for health protection.

In the various rulings of the Strasbourg Court, health protection takes on a significance that is 'derived' from other provisions of the Convention, mainly those in Articles anchoring health protection to the provisions of Articles 2, 3, and 8 of the ECHR.

Given the undeniable importance of the rulings of the European Court of Human Rights at the supranational level, especially with regard to the subject of this research, it seems appropriate to focus – albeit briefly – on the jurisprudential path taken by the Strasbourg judges[104] which, leveraging the close relationship between

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[104] In the case law of the European Court of Human Rights relating to health protection, it is possible to identify three main areas in which it is structured: firstly, so-called climate justice, in which health protection is interpreted in terms of its structural connection to environmental health. On this issue, it is worth noting the ECtHR decision of April 9, 2024, in the case of Verein KlimaSeniorinnen Schweiz and others v. Switzerland, in which a violation of Article 8 of the Convention (right to private and family life) and Article 6 (access to justice) was recognized as a result of the failure to implement policies to combat climate change. on this point, see R. Bifulco, *Emergenza e considerable weight: il cambiamento climatico nella sentenza klimaSeniorinnen,* in *www.lecostituzionaliste.it,* 2024; similarly, ECtHR, decision of January 30, 2025, Case Canavacciuolo and others v. Italy, application no. 51567/14; ECHR, decision of March 27, 2025, Case Laterza and D'Errico v. Italy, application no. 30336/22. Secondly, health has been linked to the violation referred to in Article 3 of the ECHR where the application of the statute of limitations has led to the discontinuation of criminal proceedings for ill-treatment and domestic violence; for

environmental health and the protection of individual and collective health, affirms a duty on the part of the contracting states not only to refrain from causing events that are potentially harmful to people, but also to adopt positive measures aimed at ensuring the protection of life[105].

As previously mentioned, from a purely factual point of view, it is equally important and necessary to recognize the impact that globalization has had on health protection paradigms[106]. The ease of movement of goods, services, and individuals has become extreme, allowing contagious diseases to spread just as easily. The international health crises that have characterized the beginning of the 21st century have shown us that the protection of public health can no longer be pursued through the isolated and individual actions of national states[107] .

Hence the important role of the World Health Organization, whose most important powers lie in the role it is recognized as having during epidemics that are likely to be transnational in nature.

However, as will be demonstrated in the following paragraphs, the role and effectiveness of the instruments recognized to it still seem to clash with a conception in which the traditional concept of national sovereignty struggles to lose ground.

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example, ECtHR, decision of February 13, 2025, Case PP v. Italy, application no. 64066/19. Finally, it is worth noting the case law relating to the sanitary conditions of detention centers, in which the protection of health is linked to the provision of Article 3 of the Convention; this approach is reflected in the ECtHR, decision of June 13, 2024, Case Cracò v. Italy, application no. 30782/18; ECHR, decision of November 16, 2023, Case Sadio v. Italy, application no. 3571/17; ECHR, decision of October 19, 2023, Case Locascia v. Italy, appeal no. 35648710; on this subject, see F. Masci, *Human dignity as a 'balancing factor' in the conflict between the right to health of prisoners and social security,* in DPCE online, 2, 2024.

[105] Thus A. Napolitano, *The multilevel dimension of the right to health. Protection requirements and system constraints,* Editoriale Scientifica, Naples, 2025.

[106] It should be noted that the study of the effects of globalization on human health has become the subject of an independent discipline called Global Health, whose original definition comes from the United Institute of Medicine as that set of "aspects of collective health that transcend national borders, can be influenced by circumstances or changes occurring in other countries, and can be better addressed through cooperative actions and solutions"; Institute of Medicine, *America's vital interest in global health: protecting our people, enhancing our economy, and advancing our international interest,* National Academy Press, Washington, 1997. On the concept of global health, see also F. Francioni, *State sovereignty and the protection of health as a global public good,* in L. Pisaneschi (ed.), *The protection of health in international and European law between global interests and particular interests,* Editoriale Scientifica, Naples, 2017; E. Missoni, G. Pacileo, *Elements of global health. Globalization, health policies, and human health,* FrancoAngeli, 2016.

[107] See S. Negri, *Public Health, Security, and Human Rights in International Law,* Giappichelli, Turin, 2018.

The specific subject of this chapter will therefore be a reconstruction of the legislation relating to health protection, set in the supranational institutional context. This context permeates the domestic constitutional order as a result of the two 'opening clauses'[108] contained in the Constitution itself.

Through the study of European legislation and the initiatives promoted by the WHO, we will attempt to provide a critical analysis of the conditionality that this dimension has in relation to national health protection. This is an emerging potential for conditioning, both from a purely substantive point of view, through the recognition of this right in the various Charters and their integration, and in terms of organization and healthcare.

2. *Health protection policies in the European Union.*

Consistent with the economic nature from which the European Union itself originates, the emergence of the recognition, at the regulatory level, of the right to health has followed a long and difficult path, reflecting the stages of development of the very nature of the EU. This development, especially in recent years, seems to be taking an evolutionary turn with regard to the renewed centrality that the protection of rights and the reduction of inequalities in the eurozone have acquired within EU legislation.

The path that led to the recognition of health protection in the founding treaties can be described as an upward trajectory. From the outset, with the 1957 Treaty of Rome establishing the European Economic Community, the protection of public health was identified exclusively as a limitation on the movement and exchange of goods[109].

A second phase can be identified with the enactment of acts such as the European Social Charter of 1961 and the Single European Act of 1986, in which health

[108] Consider Articles 10, 11, and 117(1) of the Italian Constitution, which allow European and international law to penetrate the legal system.

[109] Article 36 of the Treaty of Rome of 1957: "The provisions of Articles 30 to 34 inclusive shall not prejudice prohibitions or restrictions on imports, exports, and transit justified on grounds of public morality, public policy, public security, the protection of health and life of humans, animals, or plants (...)".

protection is expressly recognized. However, although it is not linked to market dynamics, it does not take on an autonomous role, as its protection is linked to the guarantee of safe and healthy working environments. This logic was anchored in the recognition of the broad scope of the role of national legislators, who had full decision-making autonomy in the allocation of resources and the determination of spending priorities.

The Maastricht Treaty of 1992 was a big turning point in this sense, with Title X all about "public health," which made healthcare a clear part of what the European Union could do. However, far from constituting an explicit area of EU intervention, the provision was essentially aimed at providing a common framework for coordinating and promoting different national policies[110].

This process reached a key point in its evolution with the adoption of the Treaty of Lisbon in 2007. In the renewed founding treaty, health protection is clearly identified as falling within the scope of competences that are exercised through initiatives to complement and coordinate the actions of Member States. In particular, it provides for a general concurrent competence in the field of public health, limited to "common safety aspects"[111], to which is added a competence of "coordination and support" recognized as belonging to the Union in the field of "protection and improvement of human health"[112], allowing it to adopt measures that complement those provided for by individual national regulations for the sole purpose of improving and coordinating them.

The division of competences between the EU and Member States in the field of health is crystallized in the provision of Article 168 TFEU. A more detailed reading of the provision in question seems to reveal a twofold dimension. The first part helps to define the Union's competence and coordination in the field of health,

[110] "The Union's action has taken the form of supporting the efficiency, quality, and resilience of the Member States' health systems through the exchange of information, the adoption of common prevention measures, and the dissemination of best practices in public health," according to A. Napolitano, *La dimensione multilivello del diritto alla salute (The Multilevel Dimension of the Right to Health),* op. cit.

[111] Article 4(2)(h) TFEU.

[112] Article 6(a) TFEU, which identifies specific areas of intervention for the European Union: "(a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; such measures shall not prevent Member States from maintaining or introducing more stringent protective measures; b) measures in the veterinary and phytosanitary fields, the primary objective of which is to protect public health; c) measures setting high standards of quality and safety for medicinal products and medical devices."

aimed at implementing the techniques put in place by individual countries to promote health protection more effectively, coordinating the various solutions adopted with a view to harmonizing the sector as far as possible[113]; on the other hand, the wording of the provision confirms the central role attributed to national legislators, whose choices are 'respected' by the EU[114].

From a purely substantive point of view, beyond the division of competences, it is the entry into force of the Charter of Fundamental Rights of the European Union that represents an important step forward in terms of health protection, which is expressly recognized in Article 35 of the Charter itself[115].

A particularly relevant element can be found in an integrated reading of the two provisions – Article 168 TFEU and Article 35 CDFEU – which provides the legal basis for the integration of health protection into all matters, a principle from which the HiAP approach derives[116]. This approach gives rise to a structure for health protection, not so much as a title of competence, but as a guiding principle for all Community policies, which must necessarily be inspired by it[117].

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[113] The areas of intervention of the European health strategy can thus be summarized as follows: prevention of disease and promotion of healthy lifestyles; facilitating access to better and safer healthcare; contributing to innovative, efficient, and sustainable health systems; addressing cross-border threats; keeping people healthy throughout their lives; exploiting new technologies and practices. See EUR-lex-public health.

[114] Paragraph 7 of Article 168 TFEU states that "Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organization and delivery of health services and medical care. The responsibilities of the Member States include the management of health services and medical care and the allocation of resources thereto." A "safeguard clause" (A. Napolitano, op. cit.) which, according to some, is "clearly intended to limit the prospective expansion of EU law in this area," as stated by S.R. Vinceti, *La tutela della salute nelle democrazie stabilizzate. Uno studio di diritto comparato (Health protection in stable democracies. A comparative law study),* Giappichelli, Turin, 2024.

[115] See D. Morana, *Prime riflessioni sul diritto alla salute nella Carta dei diritti fondamentali dell'Unione Europea (Initial reflections on the right to health in the Charter of Fundamental Rights of the European Union),* in A. D'Atena, P. Grossi (eds.), *Tutela dei diritti fondamentali e costituzionalismo multilivello. Tra Europa e Stati nazionali (Protection of fundamental rights and multilevel constitutionalism*. Between Europe and national states), Milan, 2004.

[116] "Health policy is not the only policy that is decisive in the field of health. Other policies such as the environment, research, regional policy, the regulation of pharmaceuticals and food products, the coordination of social security systems, and tobacco taxation are also essential. It is therefore important to establish synergies between all sectors that are crucial to health," according to the Commission's White Paper of October 23, 2007, entitled "Together for Health: A Strategic Approach for the EU 2008-2013" (Com(2007) 630), available on the website.

[117] "The absence of operational tools to deliver services on the one hand, and the usual propensity of European institutions for austerity policies on the other, have prevented the right to health from being given the central role that it tends to enjoy in national legal systems as a guarantee of a fundamental human right," according to C. Colapietro, *Social Rights Beyond the State. The case of cross-border healthcare,* cit.

At the EU level, the health sector has been affected by the market logic on which European legislation has traditionally been based. This has had a negative impact, so to speak, insofar as it is possible to include in this specific regulatory context the measures promoted as part of the *austerity* policy pursued at the European level in the decade following the 2008 economic crisis. The development of European welfare and, in particular, the right to health as a financially conditioned right, has inevitably been affected by these regulatory measures, which have reformulated the balance between the need to contain public spending and the protection of rights in a way that is more favorable to the former.
Reference is made, in particular, to the series of economic and financial measures aimed at promoting a policy of public spending restraint, culminating in the adoption of the Treaty on Stability, Coordination, and Governance in the European Union (the so-called Fiscal Compact[118]), which introduced the principle of balanced budgets and the prohibition of excessive debt in the Eurozone countries.
Many have interpreted this attitude on the part of European institutions as confirmation of the Union's liberalist nature, a confirmation of traditional values based on the paramount protection of the European single market and financial logic[119].

However, at the same time, a sort of 'silent revolution' seems to be taking shape[120], namely the gradual emergence and subsequent – albeit slow – affirmation of policies aimed at protecting social rights. This innovative scenario includes the legislative initiative aimed at affirming and proceduralising the healthcare mobility of European citizens, which will be discussed in the following paragraph.

[118] On this topic, see M. Di Simone, *The integration of the European Stability Mechanism and the Fiscal Compact Treaty into the European Union legal system,* in *Osservatorio costituzionale,* 1, 2018; R. Ibrido, *Coordination of budgetary decisions and public debt sustainability: reasoning on the changing economic constitution,* in *Rivista Trimestrale di Diritto dell'Economia,* 1, 2020; M. Trimarchi, *Budgetary policies and European constraints,* in *Il diritto dell'economia, 3*, 2023; A. Saitta, *'Fiscal compact' between the Constitution, treaties and politics,* in *AIC Review,* 4, 2017; F. Losurdo, *Stability and growth from Maastricht to the Fiscal Compact,* in *Legal Culture and Living Law,* 2015.
[119] A. Ciarini, L. Pennacchi, *The Future of Social Rights in Europe: Investments, Actors, and New Policies for a (Different) European Social Model. Introductory Note,* in *Riv. Pol. Soc.,* 2017, 9; S. Cecchini, *Does Europe Aspire to Become a Welfare State?,* in *Rivista AIC, 4*, 2021; A. M. Poggi, *Economic crisis and crisis of social rights in the European Union,* in *Rivista AIC, 1*, 2017;
[120] Thus S. R. Vinceti, *Health protection in stable democracies,* op. cit.

2.1 Continued. Cross-border healthcare

Although the roots of the Union's liberal tradition continue to prevail, it is necessary to emphasize the European legislator's attention to the dynamics relating to the protection of rights, in particular, in this case, the right to health.
In this scenario, Directive 2011/24/EU takes center stage, recognizing the right of patients to receive medical care and treatment in Eurozone countries, even if different from their country of origin. This intervention takes on particular significance when considered in the context of the evolution of the protection of rights in particular and, more generally, the evolution of the nature of the Union.
The evolution of health protection in the European area is embodied in cross-border healthcare mobility, which, on the basis of the division of competences in this area under Article 168 TFEU, allows for Community regulatory intervention by overcoming national borders.

The gradual recognition of this prerogative for European citizens can be analyzed from two perspectives: on the one hand, it is part of the evolutionary path of the EU itself, based on the role it has assumed in the protection of fundamental rights; on the other hand, the possibility of movement based on health needs inevitably affects the organizational structures set up at the national level, including the issue of the financing of individual national health services.

The regulatory framework for healthcare mobility, which has its origins in the logic of the single market, is divided into two regulatory tracks consisting of the provisions of the 2011 Directive and the previous provisions contained in the 2004 Regulation.

The aforementioned Directive represents the latest step in the evolution of the recognition of healthcare mobility, which began with a series of court rulings that were subsequently recognized through the issuance of a slightly earlier regulatory act, Regulation No. 833/2004.
The two regulations are structured in such a way as to prevent overlap between them, as each of them covers specific areas. There are many differences between the two sources; among the main ones, it is possible to highlight the divergence in the conditions for application, which reflects the gap between the *rationales* of the

two legislative measures: while the ultimate objective of the Regulation was essentially to clarify the relationships between social security systems, the *focus* of the Directive was to implement the subjective position of patients within the Community[121].

From a subjective point of view, while the Directive applies to all European citizens, the previous Regulation refers exclusively to workers residing in a Member State, their family members and survivors, and those pursuing studies or training.

With regard to procedural rules, it should be noted that the conditions for obtaining treatment have evolved over time, leading to the adoption of the 2011 Directive. In line with the logic of broadening subjectivity, the rules contained in the aforementioned legislation require the patient to submit the request directly to their registered health service, which, after verifying the requirements — and where the provision of authorization[122] is required — to which recognition is subject, will reimburse the expenses incurred by the patient in the country of treatment.

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[121] See L. Busatta, *Health citizenship in the European Union: the phenomenon of cross-border patient mobility, from free movement to the relational dimension of rights,* in *DPCE online, 3, 2015.* On the regulation of cross-border healthcare contained in the 2011 directive, see also G. M. Salerno, *Cross-border healthcare: issues and prospects,* in *Supreme Courts and Health,* 1, 2022; which, with regard to the differences between the regulations, states that the Directive "aims to protect the rights of European citizens to access cross-border healthcare and related reimbursement, guaranteeing the quality and safety of healthcare services provided in another Member State."

[122] On the legitimacy of the authorization regime provided for by national states, it is important to emphasize that the content of the Directive has accurately incorporated the case law of the Court of Justice of the EU. In particular, we note the rulings that have established the legitimacy of refusing authorization for cross-border healthcare in cases where: they are based on the need to ensure the preservation of the healthcare system or medical expertise in the territory of the State, essential for public health or the survival of the population (CJEU, judgment section II, April 19, 2007, case C-444/2005, Stamatelaky, "A restriction on the freedom to provide medical and hospital services is also permissible where the preservation of a healthcare system or medical expertise on national territory is essential for public health or even for the survival of the population), where it is justified by specific and particular requirements of medical and hospital systems and where it is shown that the treatment requested is provided in an identical or equally effective manner for the patient by the State in which he or she resides (CJEU, October 23, 2003, Case C-56/2001, Inizan); the refusal of authorization was also considered justified where the patient's request was based on the need for speed in obtaining treatment and such timelines could also be ensured in practice in the State of origin (CJEU, May 16, 2006, C-372/2004, Watts). Finally, at the procedural level, the characteristics that the authorization system must possess in order to be considered legitimate have been clarified: it must necessarily comply with the principles of adequacy and proportionality, it must be based on objective and non-discriminatory criteria, which must be made known in advance; it must guarantee easy access to the procedures for issuing authorizations, which must necessarily be based on an objective, legitimate, rapid, and impartial assessment (CJEU, July 12, 2001, C-157/1999); in doctrine, on the authorization regime provided for by the Directive, see E. Longo, *The right to the best healthcare in Luxembourg case law,* in *Quaderni costituzionali,* 2007; A. Di Rienzo, *The absolute exclusion of reimbursement of hospitalization expenses abroad is contrary to Community*

The Regulation differs from the latter in that it is based on a mandatory authorization system, which is in turn subject to specific requirements such as: the temporary stay of the worker or student in a Member State other than their country of origin; and the submission of an application for authorization to obtain healthcare in a healthcare facility located in the host country. The existence of an authorization system, defined as a general rule within the scope of the Regulation, is balanced by the possibility of receiving direct healthcare, which means that there is no *ex post* reimbursement of the costs incurred by the patient in the host country, as dialogue is established between the home country and the host country in order to cover the costs that the latter will incur[123].

Despite the numerous differences between the two regulations, it seems possible to identify a *common thread* in the legal basis on which they are founded. Although the Directive appears to be based on a logic of extending the right to health protection for individual EU citizens, it is also based on a logic that can be traced back to the implementation of the single market. This argument is based on the article referred to as the foundation of the secondary legislation: Article 114 TFEU, which is based on a logic primarily aimed at protecting the proper functioning of the internal market.

It is therefore possible to identify a market logic in the 2011 Directive that confirms the economic and financial nature of the Union's interests. However, unlike what happened previously, it is possible to configure an instrumental use of

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law, in *Dir. Pubb. Comp., 2*, 2007; R. Cisotta, *Case law principles and new Commission initiatives on patient mobility in the European Union: a small (or large?) earthquake is underway,* in *Studi sull'Integrazione europea, 1*, 2007.

[123] In light of European regulations, as implemented in Italian law by Legislative Decree 38 of 2014, which does not provide for a prior authorization system for access to cross-border healthcare, a further difference appears to emerge between the regulations introduced, relating to the structure of the relationship between the patient, the treating state, and the state of affiliation. The latter takes the form of a triangular relationship. In the case where the regulations described in EC Regulation 2004 are followed, "the necessary prior authorization serves to make the relationship triangular; the individual who moves abroad gives rise, at the same time, to an obligation on the part of the State of affiliation to pay the cost of the service directly," according to N. Posteraro, *Cure oltre lo Stato: l'effettività del diritto alla salute alla luce del d.lgs. n. 38 del 2014 (Care beyond the State: the effectiveness of the right to health in light of Legislative Decree No. 38 of 2014),* in *federalismi.it.* The type of relationship defined in the directive does not appear to be a trilateral relationship, but rather two different bilateral relationships: that between the patient and their country of origin and that between the patient and the country providing treatment.

this logic to affirm fundamental rights[124]. The relationship between the free market and fundamental rights has so far been articulated in a dynamic that saw the protection of rights as a negative limit to European legislation[125], reserving them exclusively for state regulation. Today, however, this relationship seems to be facing an important paradigm shift, in which healthcare mobility could represent a first testing ground. The protection of rights, although attributable to market logic, in line with the tradition of the Union, is becoming increasingly present in Community policies, not so much as a limitation on economic reasoning, but rather as an interest that increasingly transcends national borders.

Despite the good intentions, however, the provisions contained in the Directive under discussion appear to be open to certain criticisms which, in practical terms, have proved capable of adversely affecting its effective implementation.
Reference is made in particular to the systemic divergence between the individual national transposition regulations, as well as to the impact of the system thus established on the financial structure of the individual national health systems.
Both of these critical issues have been explicitly recognized in the EU legislation adopted in the wake of the pandemic[126], which focuses on a new awareness on the part of the European Union of the importance of implementing not only policies relating to health protection, but also its role in coordinating and complementing national regulations[127].

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[124] "While it is true that in most cases fundamental rights are invoked by Member States as a brake on the application of free market provisions, creating an irreconcilable conflict between them, it is also true that in some cases it is precisely the realization of the free market that has the effect of increasing their protection," according to L. Uccello Barretta, *The right to health in the European area: healthcare mobility in light of Directive 2011/24/EU,* in *federalismi.it,* 19, 2014.

[125] See G. Orlandini, *Economic freedoms and European social citizenship,* in E. Paciotti (ed.), *Fundamental rights in Europe,* Viella, 2011; R. Mastroianni, *Human rights and fundamental economic freedoms in the European Union legal system: a new balance?,* in *European Union law,* 2, 2011.

[126] On this point, see Chapter IV below.

[127] On this point, see G. M. Salerno, *Cross-border healthcare: issues and prospects, op.* cit.

2.2.Continued. Post-COVID policies: a sign of a new awareness?

The advent of the pandemic has led European institutions to adopt secondary legislation that demonstrates a different attitude on the part of the EU, characterized by the centrality given to health issues. In fact, the latter goes beyond the rigid boundaries traditionally reserved for it, such as those relating to cross-border care, and has come to occupy a predominant position at the programmatic level as well.

There are two relevant pieces of legislation: on the one hand, Regulation EU/2021/522, establishing the EU4Health Program, which includes a programmatic investment plan for the health sector; and, on the other hand, the space reserved for this subject in Regulation EU/2021/241, establishing the Recovery Fund, which, although more oriented towards the economic recovery of national states, reserves an important role for health protection.

Regulation EU/2021/522, set in the post-pandemic context, takes its cue from this[128] , constituting an important example of awareness of the insufficiency of the powers attributed to the Union in an area such as health, where the cross-border nature can no longer be relegated to marginal assumptions.

The Regulation therefore has the merit of establishing a Health Program for the period 2021-2027 in which the role of the Union appears to take on a dual dimension. On the one hand, it is recognized as having the traditional role of coordinating and complementing the protection systems set up at national level, which, in the specific context of the Regulation, appears to be specifically aimed at implementing methods for exchanging information, sharing knowledge, and strengthening the exchange of best practices between Member States[129] . On the other hand, the wording of the Regulation under discussion seems to recognize that the Union has a role beyond the coordination role it has historically been assigned. The Program provides for the strengthening of the Union's role in the specific area

[128] "The experience gained with the current COVID-19 crisis has demonstrated the need for further decisive action by the Union to support cooperation and coordination between Member States. Such cooperation should improve preparedness, prevention, and control of the spread of serious human infections and diseases across borders in order to combat serious cross-border health threats and safeguard and improve the health and well-being of all citizens in the Union." Recital 6 of Regulation (EU) 2021/522.

[129] Recital 8 of Regulation (EU) 2021/522

of cross-border health emergencies, to be implemented both through support for actions taken within the framework of existing mechanisms and structures[130] and through the strengthening of planning, preparedness, and response capacity at Union level. The latter aspect is to be achieved through support actions aimed at implementing preparedness, emergency planning, preventive measures, and enhanced surveillance programs.

Although tentatively, the legacy of the pandemic seems to have brought the European legislator a new awareness of the potential of its intervention in an area where national borders are not suitable for containing potential harm: cross-border health emergencies.

Beyond the specific competences and role assigned to the Union in the field of health protection, there is a clear desire, for the first time, to create a 'European Health Union'[131] in which citizens' health is not considered merely as a limitation on economic freedoms, nor relegated to the narrow confines of cross-border care, but becomes an autonomous area of interest in European policies.

The Regulation establishing the EU4Health Program is supplemented by the shortly thereafter adopted Regulation EU/2021/241, which introduces the Recovery and Resilience Facility to ensure, especially in times of crisis, the accessibility and capacity of health and care systems[132] .

The renewed focus of the European Union on the protection of rights is also confirmed in the subsequent Regulation establishing the Recovery Fund.

Although the main focus of this legislation is the substantial funding granted to Member States to stimulate economic recovery and the integration process following the pandemic period, it should be noted that access to this funding was conditional not only on guarantees regarding the sustainability of individual states' debt but also on a request to improve coordination between state and regional authorities in the field of healthcare.[133] .

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[130] Reference is made in particular to Decision No. 1082/2013/EU of the European Parliament and of the Council of October 22, 2013, on serious cross-border threats to health.

[131] Recital 11 of Regulation (EU) 2021/522

[132] Recital 15 of Regulation (EU) 2021/244

[133] L. Chieffi, *A new season for social rights? The boost provided by the Recovery Fund for the relaunch of healthcare welfare,* in *Bio-Law journal Rivista di Biodiritto,* 4, 2021. The author identifies as a critical point the need for centralized interventions which, in the Italian context of healthcare regionalism, can cause distortions if not carried out in accordance with cooperative

It is worth noting that the substantial economic support granted to Member States by the EU is primarily directed towards the implementation of national welfare systems[134] . According to some, this regulatory context heralds a new attitude on the part of the EU, attributable to 'inclusive liberalism'[135] , in which the relationship between rights and the market is translated into the instrumentalisation of market constraints in favour of economic and social objectives.

This is a new dimension for the protection of rights in the European space, accompanied by an awareness of the importance of the role and intervention of the EU in a sector that now transcends individual national borders, in the name and for the sake of better protection.

3. *Health protection in international law: the World Health Organization (WHO)*

The increase in epidemics of a supranational scale has demonstrated the inevitable need to institutionalize cooperation between states in the field of health. This has been a long and difficult process, hampered by legal traditions that rigidly identified the state as the only possible holder of the task of protecting its citizens[136],

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regionalism. In particular, the author indicates that 'While respecting the powers granted to regional authorities in the field of health and social-health services, there is no doubt that the use of these European funds, as planned in the PNRR, must be coordinated and constantly monitored by central government bodies. (...) while respecting the rules of cooperative regionalism, which require constant consultation with local representatives during the implementation and coordination of the measures set out in the Plan." On the impact of the PNRR on the structure of the Italian form of government, see Chapter III *below*.

[134] On the peculiarity of European legislation, see F. Salmoni, *Recovery fund, conditionality, and public debt. The great illusion,* Turin, 2021; M. Patrin, *Solidarity and cohesion between continuity and transformation. Cohesion policy as a tool of EU governance,* in *European Union Law,* 3, 2024; F. Costamagna, *The fight against poverty and social exclusion as an objective of the European Union in the relationship between the economic, social, and environmental dimensions of the integration process,* in *European Union Law, 2*, 2024; P. Gaggero, *Community programming for recovery and resilience through the prism of solidarity,* in *Review of European Public Law,* 1, 2024; A. Conzutti, *Dynamics of the European economic constitution after the pandemic crisis: new advances or old habits?* in *Consultaonline,* 3, 2024; M. Forlivesi, *Next Generation EU: a new frontier of European integration,* in *Lavoro e diritto,* 2, 2023;

[135] M. Salvati, N. Dilmore, *Inclusive Liberalism. A Possible Future for Our Corner of the World,* Milan, 2021.

[136] F. Francioni, *State sovereignty and the protection of health as a global public good,* op. cit.; in which the author, reconstructing the relationship between sovereignty and the role of the state in the protection of fundamental rights, such as the right to health in particular, attributes to the category of state obligations "the exercise of sovereignty in order to facilitate, promote, and provide for the concrete realization of the right to health through appropriate policies, legislative and administrative

culminating in the establishment of the World Health Organization, which has been granted numerous prerogatives over the years.

The path that led to what can now be identified as "international health law" stems from the recognition of health as a global public good[137], defining this category as the set of public goods whose consumption is accessible to an indistinct plurality of countries. To summarize briefly, it can be said that, according to this concept, the protection of health as thus conceived becomes comparable to a limitation on the exercise of state sovereignty, as traditionally understood[138].

As briefly mentioned above, the path that led to the adoption of this international approach was anything but swift, and it is important to briefly retrace the steps that led to this result.

The origins of the internationalization of health protection can be traced back to the first cholera epidemic on the European continent, following which the attitude of national states, until then custodians of nationally managed health policies, began to change due to the need for ultra-territorial management of the contagion[139] . The conventions signed in this context constitute the first example of international health protection, in which the obligations of individual states were exclusively to inform other states about the conditions of the epidemic in their territory and related discoveries, to which was added the duty to maintain certain health standards in places potentially most exposed to the entry of diseases, such as ports or airports.

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measures, and budgetary provisions"; in this sense, sovereignty plays the role of 'legitimate guardian of the health of the population residing on its territory'.

[137] On this subject in particular, see I. Kaul, I. Grunberg, M. Stern, *Global public goods: international cooperation in the 21st century,* Oxford Academic, 1999;

[138] F. Francioni, op. cit.

[139] Particular reference is made to the First International Health Conference, held in Paris, France, in 1851, at which the first health conventions dedicated to the harmonization of quarantine measures and the surveillance of contagious diseases were concluded; on this subject, see D. P. Fidler, *From International sanitary conventions to Global Health Security: the new International Health Regulations,* in *Chinese Journal of International Law,* 2005, Oxford University Press; the author defines this approach as a 'classical regime' attributes the emergence of international cooperation in the field of health to the need to harmonize quarantine procedures between different national states in order to better manage trade between them. In particular, the author observes that "Prior to the start of international cooperation on the spread of infectious disease, each country more or less fended for itself and quarantine of ships and travelers was virtually universal national policy response to the threat of imported disease. Merchants and traders confronted, thus, a fragmented, non-harmonized patchwork of national quarantine regulations that imposed delays and costs on trade and commerce."

This approach, based on horizontal governance between different national states, leaves unchanged the central role assigned to individual states in managing their own health conditions and constitutes a version of the principle of non-interference in the internal affairs of states. A classic state-centric regime[140] , which some attribute to the Westphalian tradition of the role of the state, giving rise to the expression 'Westphalian public health'[141] to indicate the internationally relevant limit in health matters to issues that could potentially harm trade.

The establishment of the World Health Organization in 1946 did not mark the culmination of international health protection as it is conceived today[142] . Emblematic in this sense is the first International Health Regulations issued by the same organization, which, although commendable from the point of view of harmonizing and systematizing the disciplines contained in a plurality of conventions, maintained respect for the principles of sovereignty and non-interference—typical of the traditional approach—confirming the horizontal structure of governance in international health protection.

This model entered into crisis at the end of the 20th century, when the proliferation of epidemics such as AIDS and viral fevers revealed the inadequacy of the discipline, made particularly evident by the failures of the signatory states[143] .

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[140] D. Fidler, *SARS, Governance and the Globalization of the Disease,* Palagrave MacMillan, New York, 2004, p. 26 ff.;

[141] S. Negri, *The protection of international public health between global governance, "health sovereignty" and fundamental rights,* in *Studies in honor of Augusto Sinagra,* 2013; in which it is emphasized that "The legal regime developed during this period (second half of the 19th century to the end of the 20th century), in accordance with the structure and principles of the Westphalian state-centric system, resulted in horizontal governance, in which states were willing to adopt rules limiting their sovereignty in order to mitigate the negative effects of quarantine measures on trade and travel."

[142]Established in 1946 as a specialized agency in the field of health within the United Nations, the preamble to the Constitution of the World Health Organization specifies that "The health of all peoples is fundamental to the attainment of peace and security and depends on the fullest cooperation of individuals and States. The achievement of any State in the promotion and protection of health is of value to all. The unequal development of different countries in the promotion of health and the control of disease, particularly communicable diseases, is a common danger." For more on the WHO in doctrine, see G.L.Burci, *WHO (World Health Organization),* in S. Cassese (ed.), *Dizionario di diritto pubblico,* IV, Milan, 2006; E. Greppi, *OMS (Organizzazione Mondiale della Sanità), in Novissimo Digesto Italiano,* Turin, 1987; A. Davì, *Organizzazione Mondiale della Sanità,* in *Enciclopedia del Diritto,* XXXI, Milan, 1981.

[143] In particular, it is believed that the lack of international standards to guide the definition and identification of health threats made it difficult for national states to report suspicious events to the WHO; moreover, such reporting was disadvantageous for the reporting state, insofar as restrictive measures would be applied to the latter, potentially causing adverse effects on its economy.

Following renewed awareness of the need to overcome the traditional dogma of state sovereignty in health matters, whose global nature could no longer be denied, the new International Health Regulations of 2005 represent the culmination of the evolutionary process that led to the definition of vertical international health governance, in which the Organization is recognized as having specific prerogatives in exchange for member states relinquishing portions of their sovereignty. This is a scenario whose modernity is represented by the limitations on sovereignty granted by individual nations, in which the position of the WHO itself is of central importance. Reference is made to cases of health emergencies of 'international concern', which entail duties and obligations for member states in terms of information, surveillance, and border control; in addition, there are cases in which state sovereignty is limited in order to ensure the protection of health as an international human right[144] .

Therefore, it can be said that the vertical governance of international health protection can also be identified in two dimensions, substantive and organizational. On the one hand, international health management is implemented in cases where there are health emergencies that affect different territorial areas; on the other hand, the role of the national state in protecting rights becomes secondary to that provided for in international charters and conventions[145] , insofar as the latter, due to their formulation, can guarantee better protection from a qualitative or quantitative point of view.

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[144] F. Francioni, op. cit.

[145] The substantial dimension of the protection of the right to health in the international sphere is embodied in a number of documents. First and foremost, it finds its first formal recognition in the preamble to the WHO Constitution of 1946, which states that "The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social conditions." This was followed by the Universal Declaration of Human Rights of 1948, Article 25 of which partly echoes the preamble to the WHO Constitution, expanding it to include, within the scope of health protection, the satisfaction of other needs such as food, housing, medical care, and social security. The International Covenant on Economic, Social and Cultural Rights, signed in New York in 1966, dedicates Article 12 to the right to health, which, in defining it, echoes the preamble to the WHO Constitution, but, unlike the latter, frames this right as a right to "progressive realization."

3.1 Continued. The role of the WHO in managing health emergencies of international concern

As emerges from the considerations made so far, it seems possible to recognize a predominant role for the World Health Organization in the management of health emergencies of international concern, i.e., situations in which the incidence of an epidemiological or pathological situation spills over into a territory that exceeds the borders of a single national state, finding its raison d'être in this specific context.
In fact, in the extensive list of functions assigned to it[146] , regulatory power is recognized exclusively "for the purpose of preventing the spread of disease from one country to another"[147], unlike the possibility of issuing recommendations, which may be made to Member States on any matter within the Organization's competence.

WHO regulations[148], whose legal basis lies in the provision of Article 21 of the Constitution, are the main instrument by which the Organization can prevent the spread of infection during health emergencies.
The International Health Regulations of 2005 are the latest version, the result of a long process of updates to the first version of 1961. They differ from the latter in the diversity of the approach adopted by the Organization itself, which is recognized as having a predominant and autonomous role in international regulations relating to the right to health during international emergencies.

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[146] Listed in Article 2

[147] Article 21 Constitution: "The Health Assembly is authorized to issue regulations concerning: a) health and quarantine measures or any other measures designed to prevent the spread of disease from one country to another; b) the nomenclature of diseases, causes of death, and methods of public hygiene; c) the uniform designation of diagnostic methods valid in the international field; d) standards relating to the conformity, purity, and activity of biological, pharmaceutical, and similar products in international trade; e) conditions relating to the advertising and designation of biological, pharmaceutical, and similar products in international trade."

[148] The doctrine on the legal nature of these regulations is far from settled; ranging from the recognition of these acts as unilateral acts of the Organization to identifying them as sui generis acts "halfway between internal acts of the Organization and simplified international agreements," according to S. Izzo, *Brevi considerazioni sul ruolo dell'OMS nel contrasto alla pandemia di Covid-19 [Brief considerations on the role of the WHO in combating the Covid-19 pandemic]*, in *DPCE online, 2*, 2020; on this point, see R. Virzo, *The Proliferation of Institutional Acts of International Organizations – A Proposal for Their Classification,* in R. Virzo, R. Ingravallo (eds.), *Evolutions in the Law of International Organizations,* Leiden, 2015; L. Boisson de Chazournes, *The Regulatory Power of the World Health Organization: Reflections on the Scope and Nature of the 2005 International Health Regulations,* in *Law of Power, Power of Law: Essays in Honor of Jean Salmon,* Brussels, 2007.

The wording of the provisions contained in the aforementioned Regulations allows the WHO to be given full centrality in the management of such contexts. On the one hand, it is identified as the main and specific recipient of a series of mandatory communications incumbent on national states, which are also subject to a series of obligations to cooperate and provide continuous information to the Organization on the data collected[149] ; thanks to which it is able to carry out the fundamental role of general surveillance assigned to it. On the other hand, the Regulation provides for the possibility for the Secretary-General of the Organization to declare a "public health emergency of international concern"[150] (PHEIC). This declaration leads to the appointment of a committee—called the Emergency Committee—with advisory functions, as well as the possibility for the Director-General to adopt temporary recommendations, addressed both to the State affected by the PHEIC and to third States, concerning containment and control measures[151] .

Legal scholars have pointed out that the nature of the recommendations is a compromise between the need for the WHO to play an effective role in managing

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[149] Pursuant to Article 6 of the IHR, "Each State Party shall assess events occurring within its territory (...). Each State Party shall notify the WHO (...) of all events that may constitute a public health emergency of international concern within its territory"; "Following notification, a State Party shall continue to promptly communicate to the WHO the public health information available and relevant to the notified event in a sufficiently precise and detailed manner, including, if possible, case definitions, laboratory results, source and type of risk, number of cases and deaths, conditions affecting the spread of the disease, and health measures taken; it must also communicate, if requested, the difficulties encountered and the support needed to respond to the potential public health emergency of international concern."

[150] Pursuant to Article 12 of the Regulation, following information received from the State Party where the event is occurring, the Director-General may declare that the event constitutes an international emergency on the basis of specific requirements and obligations set out in paragraph 4 of that Article, which include "the information received from the State Party; the opinion of the Emergency Committee; scientific principles and available scientific evidence and other relevant information; an assessment of the risk to human health, the risk of international spread of disease, and the risk of interference with international traffic." The wording of the provision highlights the role assigned to the State Party where the event occurs, which, pursuant to paragraph 3 above, must be party to the agreement with the Director-General in order to declare a public health emergency of international concern within 48 hours.

[151] The Director-General's regulatory power is exercised through the possibility of adopting two different types of acts: temporary and permanent recommendations. Temporary recommendations under Article 15 "may include health measures to be implemented in the State Party where a public health emergency of international concern has occurred or by other States Parties, relating to persons, baggage, cargo, containers, means of transport, and/or postal parcels to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic." According to Article 49, which governs the procedure for their adoption, "they may be terminated at any time and shall automatically expire three months after their promulgation." Permanent recommendations, pursuant to Article 16 below, have the same purpose as temporary recommendations, differing only in that the WHO has the exclusive right to terminate their effectiveness only "when deemed appropriate."

the emergency situation and the need to maintain some sovereignty for member states[152] .

The autonomy of member states in such contexts is preserved by the Regulation itself, which, although representing an evolutionary development in international health protection regulations, nevertheless suffers from the structural difficulties inherent in internationalist regulations relating to the inability to establish global health governance[153]. On the one hand, reference is made to the margin of autonomy provided for by the provisions contained in the Regulation itself, according to which Member States may introduce additional health measures[154] to those recommended by the WHO, provided that they are equally or more effective, but only if they do not impede international traffic. On the other hand, the 'sovereign' role recognized for state bodies derives from the Treaty establishing the Organization itself, Article 22 of which provides for the possibility for member states to notify the Director-General of their rejection or reservation of regulations issued by the Assembly pursuant to Article 21 within six months of their approval. This mechanism, known as opting out, undermines the effectiveness of the measures issued by the Organization, reducing their scope of application to only those States that consent to them. Added to this is the impossibility of implementing

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[152]G. L. Burci refers to a "compromise between the need for centralized coordination of prevention and response activities and the safeguarding of the sovereignty of States Parties that did not wish to abandon the possibility of adopting unilateral protective measures" *in Tutela della salute ed evoluzione della sicurezza collettiva* (Health Protection and the Evolution of Collective Security), in L. Pisaneschi (ed.), *Health Protection in International and European Law between Global and Particular Interests,* Editoriale scientifica, 2017.

[153] See in particular F. Francioni, *State sovereignty and the protection of health as a global public good,* op. cit.

[154] The "Additional Health Measures" are governed by Article 43 of the IHR, which explicitly clarifies that "This Regulation shall not prevent States Parties from implementing health measures in accordance with their national legislation and obligations under international law"; However, this prerogative is subject to the fact that such measures '(a) achieve the same or higher level of health protection than the WHO recommendations; or b) are otherwise prohibited under Article 25, Article 26, paragraphs 1 and 2 of Article 28, Article 30, paragraph 1 c) of Article 31, and Article 33, provided that they are otherwise consistent with this Regulation."

sanctioning mechanisms[155] where States allege violations or fail to comply with their obligations under the regulations adopted within the WHO[156].

3.2 Continued. The World Health Organization and the pandemic emergency: the new Treaty.

In this regulatory context, it is possible to trace the ways in which the WHO has attempted to contain and regulate the Covid-19 pandemic.
Based on the provisions contained in the Regulations as updated in 2005, the Chinese authorities informed the WHO on January 31, 2019, about the presence of cases of pneumonia in their territory. Following what some described as a skeptical attitude on the part of the Organization's internal bodies[157], the public health emergency of international concern was only declared on January 30, 2020 (pursuant to the provisions of Article 12 of the IHR), followed by the declaration of a pandemic on February 11.

[158]Once the Organization became aware of the scale of the health emergency, it attempted to put in place a series of measures in the form of recommendations to member states containing guidance on the health measures deemed most appropriate to slow the spread of the infection, as well as the need to

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[155] The possible option of adopting countermeasures against the defaulting State is considered difficult to implement given the absence of such power in the Treaty establishing the Organization itself; on this subject, see A. Spagnolo, *Countermeasures by the World Health Organization as a consequence of violations of international health regulations in epidemic contexts,* in L. Pisaneschi (ed.), *Health protection in international and European law between global interests and particular interests,* Editoriale Scientifica, 2017; which identifies Article 7 of the WHO Constitution as the only possibility for sanctions against Member States, applicable only in cases of non-compliance with financial obligations; M.L. Picchio Forlatti, *Sanctions in international law,* Padua, 1974

[156] *Report of the Review Committee on the Role of the International Health Regulations* (2005) in the Ebola Outbreak and Response of May 13, 2016, emphasized that "the ethos that underpins international public health fora is one of cooperation and collaboration, rather than sanctions." V.apps.who.int/gb/ebwha/pdf_files/WHA69/A69_21-en.pdf?ua=1.

[157] See, in particular, S. Izzo, *Brief considerations on the role of the WHO in combating the pandemic,* in *DPCE online,* 2, 2020.

[158] The Emergency Committee noted that, under the IHR, States are "legally required" to share information with the WHO [Statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV), January 30, 2020].

share any useful data or information between member states and the Organization itself.

Despite this, these guidelines have not been fully followed by member states. On the one hand, China has not fully complied with its notification and communication obligations as the state in whose territory the event occurred, thus slowing down the response to the spread of infection and increasing the already wide margin of uncertainty about the consequences of the disease.

On the other hand, all Member States have introduced highly effective regulations to combat the pandemic, restricting the movement of both people and goods, thus severely restricting international traffic[159].

Given the situation of absolute uncertainty that has characterized both the response of national states and that of the WHO throughout the long pandemic period, it was deemed necessary to introduce a new instrument of international law aimed specifically at identifying, on the one hand, the specific regulations to be implemented in the event of epidemics and, on the other hand, to encourage states to implement policies aimed at improving their health systems with a view to increasing their ability to manage emergency situations such as the one that has actually occurred.

This initiative took shape with the appointment of an intergovernmental negotiating body tasked with drafting a new WHO pandemic treaty.

Although the content and significance of this act cannot be assessed in concrete terms at present, as it has not yet entered into force—due to reservations expressed by some States Parties, including Italy[160] —it seems appropriate to

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[159] It should be noted that Italy has blocked all flights to and from China since January 30 (www.salute.gov.it/portale/nuovocoronavirus/). With specific reference to the measures adopted by the United States, see L. O. Gostin, J. Hodge, L. F. Wiley, Presidential Powers and Response to COVID-19, available at jamanetwork.com/ For an overview of the various restrictive measures adopted by many countries, see A. Salcedo, S. Yar, G. Cherelus, *Coronavirus Travel Restrictions, Across the Globe,* available at www.nytimes.com/article/coronavirus-travel-restrictions.html In this regard, please also visit the websitewww.comparativecovidlaw.it. For the measures implemented by the EU, Italy, Spain, Belgium, and France, *see* Chapter IV.

[160] The reasons for the abstentions of 11 countries, including Russia, Iran, Singapore, Romania, Bulgaria, and Italy, are purely political, as can be seen from the words of Health Minister Schillaci: "With today's abstention, Italy intends to reaffirm its need to assert the sovereignty of states in addressing public health issues." on point B. Gobbi, *WHO pandemic plan, this is why Italy abstained (along with ten other countries),* ww.ilsole24ore.it, May 2025.

proceed, albeit briefly, with an analysis of the most innovative aspects emerging from the text of the legislation under discussion.

Although sovereignty in the field of health protection is recognized as belonging to national states as the first point of the preamble, the Treaty aims to strengthen the role of the Organization in pandemic situations, imposing numerous obligations on states to implement instruments of cooperation and information exchange with the aim of reducing inequalities between countries, which contribute to the increase in epidemics[161]. On the other hand, while recognizing the principle of national sovereignty as the guiding principle of the legislation[162], the Treaty contains very detailed obligations for Member States with a view to increasing the resilience of national health systems. In fact, it provides for obligations concerning the "preparedness, readiness, and resilience of the health system"[163] ; healthcare and social care personnel[164] , including the strengthening of regulatory systems[165] .

It therefore seems possible to affirm that the WHO has finally become aware of the global nature of health issues, which it has attempted to address by establishing a regulatory framework in which the centrality of the guidance it provides to Member States can be appreciated. However, even in this case, in view of the interference of these guidelines, the primacy of the sovereignty that each national state possesses within its jurisdiction is reiterated several times in the same regulatory text.

Therefore, although it can be said that the new Pandemic Treaty is an advanced example of international legislation on health protection, even in this case, the Organization's intention is faced with the structural limitations of international law, which sees the sovereign power of the nation as an insurmountable barrier.

[161] Article 4, paragraph 2: "Each party shall progressively strengthen its pandemic prevention measures and capacities and coordinated multisectoral surveillance (...) taking into account its own public health priorities and international standards and guidelines."

[162] Article 3, paragraph 1: "To achieve the objective of the WHO Pandemic Agreement and implement its provisions, the parties shall, inter alia, adhere to the following principles:

1. The sovereign right of States, in accordance with the Charter of the United Nations and the principles of international law, to legislate and implement legislation within their jurisdiction," to which are added the principles of solidarity, equity as an objective, respect for international law, and the best scientific knowledge as a basis for decisions.

[163] Article 6.

[164] Article 7.

[165] Article 8.

4. *Conclusions: impact of supranational legislation on the substantive and organizational dimensions of the right to health.*

In light of the considerations made thus far, it is therefore possible to decline supranational health protection, as established within the European Union and in the international regulations of the World Health Organization, in its dual role of substantive protection of the right and organizational dimension.

From a purely substantive point of view, it can be said that the proliferation of international charters, conventions, and agreements in which the right to health is enshrined does not seem to be hindered by the national dimension of the protection of rights, with which it rather has a relationship of mutual integration in order to provide the best possible protection for rights. This principle is explicitly recognized in the EU Treaties[166] and also applies to the World Health Organization, whose regulations and role take on specific importance in cases where the application of international law may result in greater protection for the same right than that recognized under national law.

The importance of supranational regulations on the right to health can also be appreciated from an organizational point of view, as they have a more or less direct impact on the management and organization of the various national health systems.

In this sense, it is possible to appreciate the role of the EU in the coordination and harmonization of different national regulations, which culminates in legislation that allows cross-border healthcare in different Member States for all European citizens, thereby affecting the healthcare expenditure of nations.

An incisive role can also be attributed to the WHO, whose regulations have an impact on healthcare organizational systems with a view to promoting improvements. In addition to this prerogative, the Organization has powers in the field of health emergencies of international concern, a factual assumption from which a series of prerogatives are derived, such as, in particular, the possibility of

[166] Particular reference is made here to the provision of Article 52 of the Nice Charter.

issuing temporary or definitive recommendations indicating to national states the measures to be taken in their respective territories.

The influence that supranational regulation has on health protection – both substantive and organizational – is as undeniable as it is necessary. As indicated in the previous paragraphs, both health and the threats that undermine its protection have definitively taken on a dimension that transcends individual national borders, making it a global asset.

Substantive and organizational protection seems to be taking on an innovative connotation, no longer being achieved exclusively through performance obligations on the part of public institutions, but rather through the granting of limitations on state sovereignty in favor of supranational entities[167].

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[167] Thus A. Spagnolo, *Countermeasures by the World Health Organization as a consequence of violations of international health regulations in epidemic contexts,* in L. Pisaneschi (ed.), op. cit.

CHAPTER III

THE TERRITORIAL STRUCTURE OF HEALTH PROTECTION

SUMMARY: 1. Composite states and the protection of rights: territorial organization as a tool for implementing rights – 2. The Italian legal system: from law to the Constitution and current challenges. – 2.1 Continued. The principle of territoriality in the 1978 legislation and subsequent reforms. – 2.2 Continued. The 2001 reform and the constitutionalization of Essential Levels. – 2.2.1. Continued. Essential levels of care: between uniformity and differentiation in the protection of rights. – 2.3 Continued. Recent challenges facing the Italian health care system: the "Mission Six" of National Resilience Plan and the (possible) implementation of differentiated regionalism. –3. The Spanish legal system and the reasons for comparison – 3.1. Continued. The protection of health in Spain: right or principle. – 3.2. The division of powers in health matters. – 3.3 Health organization in Spain. – 4. Concluding remarks.

1. Composite states and the protection of rights: territorial organization as a tool for implementing rights

As we attempted to highlight in the previous chapter, the regulatory process that led to the recognition of the right to health as a social right resulted in an awareness of the need to establish a system to enforce this right through a series of public structures and services that inevitably involve a significant outlay of public money.

As we have seen above, the issue of financially conditioned rights, which has emerged with particular force in recent decades, has often been accompanied by the need to set up complex organizational structures within the state, capable of both ensuring the effectiveness of the right and limiting the impact of public spending through the provision of mechanisms for the co-participation of local authorities[168].

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[168] A. Pioggia, *The right to health put to the test of differentiation: autonomy, organization, inequality,* in *Institutions of Federalism,* 1, 2020; in which the author highlights how the relationship between organization and uniformity in the specific sector of rights to services, and therefore financially conditioned, appears to be centralized solely on organizational efficiency, neglecting "the impact of organization not only on the effective enjoyment of the right, but also on its definition," arguing that organizational autonomy, 'if not properly governed, can determine a different form of law and therefore an inequality that is, so to speak, structural and not merely contingent'.

With the aim of analyzing the organizational structure designed to give effect to and implement the protection of a "fundamental" right, this chapter will focus on the analysis of the organizational structure of the Italian National Health System, which, since its inception, has intertwined its evolutionary dynamics with those relating to the form of regionalism attributable to the legal system.
Based on an assessment of the dynamics between the central state and autonomous regions in the protection of the right to health, analyzed in light of the evolution of Italian healthcare legislation, we will attempt to provide a comparative study with the system established by the Spanish legal system. The latter is identified as the legal system to be compared because, although it has characteristics similar to the Italian one, it is characterized by being a regional legal system characterized by the autonomy of the respective communities into which the national territory is divided. In light of the comparative analysis between two models of regional states that differ in terms of the autonomy granted to local authorities, an attempt will be made to provide a definition of the relationship between the role of the central state, as the main entity responsible for the protection of rights, and that granted to local authorities, which, although purely organizational, is capable of influencing the protection of rights as a whole.

Furthermore, the specific area of health protection seems to be the best sector in which to carry out an analysis aimed at understanding the different movements of composite states, given the mutual interdependence between the protection of rights and organization[169]. This is a relationship of dependence designed to ensure, first and foremost, effective protection of rights and, secondly, formal recognition of the role of local authorities in the institutional and organizational structure of legal systems.
The protection of fundamental rights in modern legal systems finds its essential point of reference in the principle of equality: everyone must enjoy the same rights equally, without distinctions of any kind.
The principle of equality, as recognized in modern constitutional charters, actually

[169] In the words of the Court, 'organization and rights are mirror images of the same subject matter, each implying and conditioning the other. There is no organization that, directly or at least indirectly, is not aimed at rights, just as there is no right to service that is not conditioned by organization', judgment no. 383 of 1998, Constitutional Court.

consists of two different dimensions: in addition to the formal dimension, which precludes the possibility of any kind of differentiation, there is also the substantive dimension, which, to some extent, requires differentiated treatment in order to meet diverse needs. Therefore, it seems possible to say that the territorial articulation of the protection of rights can play a h l role in this sense, finding its roots precisely in the traditional two-dimensionality of the principle of equality: uniformity and differentiation.

2. *The Italian healthcare system: from law to the Constitution and current challenges*

The Italian regional state model, specifically in the healthcare sector, although still seems vague and uncertain today, is a model whose study allows for a greater understanding of the dynamics related to health protection in cases where it is placed in contexts in which the needs of uniformity are opposed to those of autonomy.

The roots of the Italian regional state model lie precisely in the healthcare sector[170]. It is also worth noting the connection between the transfer of functions in this area to the regions and the start of the regionalization process in the 1970s[171], following which the regions were transferred responsibility for "healthcare and hospital care" in accordance with the original provisions of Article 117 of the Constitution.

Territoriality is also one of the key principles underpinning the law establishing the National Health Service, which, as discussed in the previous chapter, marks a turning point in many respects: for the first time, it established a health service financed by general taxation and aimed at all citizens, thus distancing itself from

[170] "The regions have used the powers they have acquired in the health sector to strengthen their identity and establish themselves as political and institutional actors in all areas of the national political arena." Thus F. Taroni, *Health and regions in a national health service,* in M. Salvati, L. Sciolla (eds.), *Italy and its regions,* Treccani, 2015

[171] L. Cuocolo, A. Candido, *The uncertain evolution of healthcare regionalism in Italy,* in *Quaderni Costituzionali,* 2013; highlights how "The healthcare reform process of the 1970s went hand in hand with the implementation of regionalism. In 1970, ordinary statute regions were established with concurrent legislative powers in the field of healthcare and hospital care."

the previous mutualistic system[172] , while at the same time enshrining the concrete implementation of the constitutional provision of Article 32.

Following numerous reforms implemented and attempted at the regional level, the Italian regionalization process culminated in the constitutional reform of 2001, which, on the one hand, had the merit of "crystallizing" in the fundamental text the achievements of regionalism already experimented with in the health sector and, on the other hand, constituted an attempt to export this model of regionalism to other sectors concerning the protection of social rights. Through the reformulation of the division of powers between the state and the regions – provided for in the revised text of Article 117 of the Constitution – the introduction of the principle of subsidiarity and the elimination of the national interest clause, the 2001 constituent assembly decisively demonstrated its desire to give a regional character to the Italian state, which, until then, had been organized internally on a purely administrative basis.

However, the results of the 2001 reform were less effective than expected, giving rise to a system in which the gap between the material constitution and its written version is widening[173]. While the text recognizes regions as entities with legislative powers equal to those of the state, whose autonomy is potentially subject to differentiation and further development under the newly introduced Article 116(3) of the Constitution, it reveals a fragility whose roots can be traced back to historical and cultural reasons that have given rise to a composite system in which, twenty years after the reform, the regions are unable to find a clear institutional space and are often relegated to the role of mere implementers of policies decided at the central level[174].

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[172] C. Giorgi, *Health for All: History of Healthcare in Italy from the Postwar Period to Today,* Editori Laterza, 2025;

[173] A. Morrone, *The Constitutional Court rewrites Title V,* in *Quaderni Costituzionali,* 2003.

[174] On this subject, there are conflicting positions among legal scholars such as A. Barbera, who attributes the partial implementation of Italian regionalism to the absence of socio-cultural roots that truly distinguish the national territory into different regions; thus A. Barbera, *Il peccato originale delle regioni (The Original Sin of the Regions),* in R. Bin, F. Ferrari (eds.), *Il futuro delle regioni (The Future of the Regions),* Editoriale Scientifica, Naples, 2023; *contra* M. Salvati, L. Sciolla, *Introduction,* in Aa. Vv., *L'Italia e le sue regioni (Italy and its Regions),* Treccani, 2015; according to the authors, although "the regional institution (initially) appears to be historically surreptitious (...) the regions now constitute the institutional hub of European communication networks, the point of reference for development plans, extra-European agreements, food product certification, etc."

This trend in relations between the center and the territories is particularly evident at the present moment in history: from the totally centralized management of the health emergency[175] to the structure for the implementation and management of the National Recovery and Resilience Plan, in which there appears to be no institutional space reserved for the regions, even though territoriality is a central element of the various reforms, both because the various areas concerned can be traced back to sectors of concurrent or residual competence and because of the explicit reference to 'territorial cohesion' as a pillar of the entire Plan.
In light of these introductory considerations, the following paragraphs propose an analysis of the decentralized structure of the National Health Service, analyzing the original regulations and those resulting from the reforms that affected the 1978 law, then moving on to the structure and innovations introduced in the health sector with the reform of Title V, concluding with a look at recent challenges concerning health protection, such as the reforms provided for in the NRP and the prospect of implementing differentiated autonomy.

The aim of this analysis is to highlight the dissonance between the literal wording of the Constitution, which sees the regions as institutional entities with legislative power, and a system of central-territorial relations based on the principle of loyal cooperation, and a recurring situation in which territorial autonomies are used as auxiliary administrative bodies to implement policies decided at the central level.

This instrumental use of the regions is presented as a possible model for ensuring the uniform protection of a fundamental right such as health.

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[175] *Infra* chap. IV;

2.1 Continued. The principle of territoriality in the 1978 legislation and subsequent reforms.

The principle of territoriality[176] has permeated the regulation of health protection in the Italian legal system since its inception. The very law establishing the National Health Service, in its first article, assigns the implementation of the NHS to the State, the regions, and local territorial entities, guaranteeing the participation of citizens. Preceded by the health reforms of the 1970s, with which it shares a commitment to guarantees and the desire to develop healthcare from a territorial perspective, the 1978 law aims to rationalize and complete the work begun by those reforms.

The territorial structure of healthcare can be found in the Italian legal system even before the formal transfer of powers. On this point, some regional legislative initiatives are worthy of attention, which aimed to develop "innovative models of organization and services, born out of the demands of movements and/or the experiences of local authorities, often spread across regions with different political orientations"[177]. In particular, Lombardy Regional Law No. 37 of 1972 established local health consortia responsible for coordinating between municipalities in the management of their powers in the areas of public health, environmental health, and occupational medicine[178].

In view of numerous decrees transferring administrative functions relating to "hospital and health care" to the regions[179], the organization of the National Health Service crystallized in Law No. 833 provides for a division of powers between the State and the regions with well-defined contours.

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[176] G. G. Carboni, *The right to health and territorial equality,* in *federalismi.it,* 8, 2020; refers to the "principle of territorial decentralization" to indicate the regionalization of the healthcare system.
[177] Thus F. Taroni, *Before and after that difficult December 1978,* in *Supreme Courts and Health,* 3, 2018.
[178] Article 1 of Regional Law No. 37 of 1972 provided for the automatic dissolution of these bodies "upon the establishment of local health units," specifying in the following Article 2 their function, which is to initiate and promote "the participation of local communities in the preparation of health care reform." On this point, see F. Taroni, *Health, healthcare, and regions in a national health service,* in M. Salvati, L. Sciolla, *Italy and its regions. The republican era,* vol. I, Rome, Istituto dell'Enciclopedia Treccani, p. 411 ff.
[179] Reference is made in particular to Presidential Decree 4/1972 and Presidential Decree 616/1977, the latter of which defines "health and hospital care" as a set of functions that "concern the promotion, maintenance, and recovery of the physical and mental well-being of the population."

This was a hierarchical healthcare organization in which the central government was responsible for general coordination, the regions were responsible for territorial supervision, and originally the core of healthcare was provided by local health units, which were the responsibility of the municipalities[180] .
In particular, the original regulations envisaged a role for the central government in planning and directing national healthcare policy, which was implemented through the development of the National Health Plan. The regions were responsible for planning and coordinating hospital and territorial healthcare, while the municipalities were given direct responsibility for the Local Health Units (USL)[181].
However, the markedly 'regional' nature of the Italian National Health Service was achieved following the 1992 reform, which made a series of changes to the original regulations, focusing on two main objectives: the regionalization of the health system on the one hand, and corporatization on the other, with the ultimate aim of reducing the public expenditure required to finance the National Health Service.
The original organization envisaged by the healthcare system was defined as a 'cascade' model[182], which can be interpreted in two ways.
On the one hand, from a purely organizational point of view, the planning system based on the integration of health plans developed at the state and regional levels is particularly relevant: the National Health Plan contained the general guidelines and organization, to which were added the services falling within those levels—initially uniform and subsequently essential—of care that had to be guaranteed in a uniform

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[180] Pursuant to Article 15(1) of Law No. 833 of 1978, the Health Unit was defined as "an operational structure of municipalities, either individually or in association, and of mountain communities"; on the role of municipalities in the original regulation of the National Health Service, see F.M. Lazzaro, *La partecipazione dei comuni nell'esercizio delle funzioni sanitarie e sociali (*The participation of municipalities in the exercise of health and social functions)*,* in R. Balduzzi, G. Di Gaspare (eds.), *Sanità e assistenza nel nuovo Titolo V (Health and care in the new Title V*), Milan, 2002.
[181] F. Taroni, *Before and after that difficult December 1978,* in *Supreme Courts and Health,* 3, 2018; E. Menichetti, *Health protection between 'divided' competences and 'agreed' interests. Reflections on the fate of the national health service in the new Title V of the Constitution,* in R. Balduzzi (ed.), *Italian healthcare between essential levels of care, health protection, and the devolution project,* Milan, 2004, p. 232 ff.; more generally on the evolution of the model, R. Ferrara, *The healthcare system,* Turin, 2007, p. 39 ff.; C. Bottari, *Health protection and healthcare organization,* Turin, 2009, p. 15 ff.
[182] Thus L. Cuocolo, A. Candido, op. cit.

manner throughout the national territory to avoid excessive inequalities between citizens[183].

The provisions contained in the National Plan were supplemented by those contained in the Regional Plans, which had to comply with it in terms of organization. It should be noted, with a view to analyzing the methods of integration between the regions and the central government, that the drafting phase of the National Health Plan also provided for forms of involvement by the regions: the PSN was formally adopted by the government, after consultation with the relevant permanent parliamentary committees, in agreement with the Permanent Conference for Relations between the State, Regions, and Autonomous Provinces[184].

However, the 'cascading' nature of the system can also be seen in its financing mechanism, which is set up through the National Health Fund, which is divided into various Regional Health Funds according to specific parametric criteria.

However, the regionalization process that took place in the 1990s brought about improvements in regional autonomy in the health sector, including the possibility for regions to provide for forms of self-financing of their own health systems, which became necessary in order to make available all those health and welfare services that were additional to those defined in the National Plan as Essential Levels. The reforms that took place a decade after the establishment of the National Health Service can be said to be aimed at reshaping the role assigned to the regions, based on a dynamic of involvement, collaboration, and financial co-responsibility in the management of healthcare services between the center and the territories, all with a view to greater financial sustainability of the entire system.

A key point of the reforms of the 1990s was the introduction of Essential Levels of Care, initially determined in conjunction with the national health fund depending on the availability of public financial resources and subsequently identified as the minimum threshold of care services to be guaranteed uniformly throughout the country. This measure was subsequently transposed into

[183] The question of the hierarchical relationship between the Regional Health Plan, which is bound, pursuant to Article 52 of Law No. 833/1978, to comply with the National Health Plan, even though the former was adopted by regional law and the latter took the form of a government act and was therefore a secondary source, has been debated in doctrine.

[184] Thus Article 1 of Legislative Decree 502 of 1992.

constitutional law – as will be explained in more detail in the following paragraph – with the constitutional reform of 2001, becoming the central element of the healthcare regionalism process, which allows the differences between the various regional healthcare systems to be balanced with the need for uniformity deriving from the principle of equality. As already mentioned, the LEAs were first provided for in legislation in Legislative Decree 502 of 1992, Article 1 of which provided for their definition within the National Health Plan, which, in accordance with the principle of loyal cooperation, is adopted by the Government following agreement with the Unified Conference. This legislative provision supports the legitimacy of the legislator's choice to determine the LEAs in concrete terms through the different instrument of the Dpcm, a non-legislative act of sub-primary rank, whose flexibility allows for a more suitable adaptation to the subject matter in question, which is characterized by constant evolution. First defined by the Prime Ministerial Decree of November 29, 2001, amended following the new Health Pact of 2006, and most recently updated by the Prime Ministerial Decree of 2017[185].
To date, the latter intervention, in order to ensure the updating of the healthcare system and guarantee the efficiency, quality, and appropriateness of services, has set up two commissions and a committee[186].

Although the ultimate purpose of the essential levels instrument is to ensure the ontologically necessary uniformity in the protection of a fundamental right recognized for all citizens[187], this expedient was created to calibrate the possibility

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[185] On the 2017 update of the LEA, see M. Bergo, 'I *nuovi livelli essenziali di assistenza. Al crocevia tra tutela della salute e l'equilibrio di bilancio' (The new essential levels of care. At the crossroads between health protection and budgetary balance),* in *Rivista AIC, 2*, 2017.
[186] Reference is made to the Commission for Monitoring the Implementation of the Prime Ministerial Decree established by Decree of the Minister of Health of January 19, 2017, which is responsible for ensuring the implementation of the decree, verifying its uniform application throughout the country and the financial sustainability of the full and uniform provision of essential levels of care. The second commission (National Commission for the updating of LEA), established by Article 1, paragraph 556, of Law No. 208 of 2015, most recently regulated by the Prime Ministerial Decree of 2017, is aimed at updating the LEA and promoting the appropriateness of the National Health Service in line with scientific and technological developments.
The Standing Committee for the Verification of the Provision of Essential Levels of Care (LEA Committee) was established by decree of the Minister of Health in 2005, whose tasks were subsequently expanded following the new Health Pact between the State and Regions 2012-2013 and the subsequent one of 2014-2016. to date, the Committee is responsible for monitoring the appropriateness, effectiveness, and quality of the provision of LEA.
[187] The doctrine on the subject of Essential Levels is very broad. For further information on the correlation between LEP and the concept of citizenship, please refer to M. Luciani, *Social Rights and Essential Levels of Public Services in the Sixty Years of the Constitutional Court,* in *Rivista AIC,*

of introducing forms of territorial differentiation, marginalizing them as "additional" or "supplementary" services[188] compared to those established at the national level. They are therefore aimed at implementing the regional role within a national health system that is recognized as a set of regional systems[189]; while maintaining strict compliance with the standard, set at the central level, which necessarily had to be applied in all the different regional health systems. However, despite the legally binding nature of the healthcare standards set out in the LEAs, the system thus outlined has proved to be capable of introducing inequalities in the effective protection of rights from a territorial point of view. This inequality stemmed from the possibility for regions to self-finance, within their respective regional healthcare systems, services that went 'beyond' those provided for by the LEAs.

The Essential Levels instrument was confirmed and implemented by the subsequent legislative intervention no. 229 of 1999, introducing mechanisms for verifying and controlling the quality, economic adequacy, and actual usefulness of the services included in the LEAs[190], identifying them in this sense as a 'regulatory device functional to the systemic maintenance of the right to health'[191].

The legislative decree of 1999, aimed at reforming the healthcare system once again – known as the *third* reform – came into force a few years after its predecessor, with which it is consistent in some respects, while in others it seems to suggest a reversal of the trend.

From the first point of view, with a view to greater involvement of local authorities in healthcare organization, the new legislation provides for renewed forms of involvement of municipalities in this sensitive sector, which were almost

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3, 2016; E. Pesaresi, *The determination of essential levels of services and the subject of 'health protection': the indivisible projection of a unified concept of citizenship in the era of institutional decentralization,* in Constitutional Jurisprudence, 2, 2006; A. D'Aloja, *Rights and Autonomous State. The model of Essential Levels of Services,* in Dir. Pubbl., 16, 2004

[188] A. Pitino, *Autonomies and health,* op. cit.

[189] Pursuant to Article 1, paragraph 1, of Legislative Decree 502 of 1992, as amended by Legislative Decree 229 of 1999.

[190] See L. Vandelli, C. Bottari, *Health Protection, Health Planning, and Definition of Essential and Uniform Levels of Care,* in F. A. Roversi Monaco (ed.), *The National Health Service,* Santarcangelo di Romagna, 2000; E. Balboni, *The concept of 'essential and uniform levels' as a guarantee of social rights,* in *The institutions of federalism, 6*, 2001.

[191] Thus A. Napolitano, *The multilevel protection of the right to health,* cit.

completely excluded from healthcare organization as a result of the 1992 law[192]. In accordance with the vertical dimension of the principle of subsidiarity, which is not limited to providing for the involvement of the level of government closest to citizens, but requires the establishment of forms of inter-institutional coordination[193]. The newly introduced regulations governing the Permanent Conference for Regional Health and Social Care Planning, a tool provided for by the legislator to ensure the involvement of municipalities in the regional functions of planning and evaluating regional health policies, appear to be based on this principle. By ensuring the participation of representatives of local authorities[194], the Conference is responsible for approving the draft Regional Health Plan and verifying its implementation at the local level[195].

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[192] F. M Lazzaro, *The participation of municipalities in the exercise of health and social functions,* in R. Balduzzi; G. Di Gaspare (ed.), *Healthcare and assistance after the reform of Title V,* Giuffrè, 2002; according to whom "Without doubt, the entry into force of the 1992 reform marks the lowest point of local participation in the health service."

[193] "Where, *on the other hand,* the reform innovates significantly with respect to Legislative Decree 502 of 1992 is in the involvement of municipalities in the planning and evaluation of the service, which is the responsibility of the region, an interesting aspect that leads us to address a second aspect of the principle of subsidiarity. The full implementation of this principle does not consist solely in the correct allocation of functions to the most appropriate level of government, i.e., the one closest to the citizens, but presupposes a system of relations between the various local authorities inspired not by a rigid separation of competences but by collaboration and consultation, where there are instruments and forums for coordination that allow even those functions not assigned to the authorities closest to the citizens to be exercised with the cooperation of the latter." according to D. Paris, *The role of the regions in the organization of health and social services six years after the Reform of Title V: division of powers and the principle of subsidiarity,* in *Le Regioni,* 6, 2007.

[194] Pursuant to paragraphs 2 *bis* of Article 2 of Legislative Decree 502 of 1992 (introduced by Legislative Decree 229 of 1999), "regional law establishes and regulates the Permanent Conference for Regional Health and Social Care Planning, ensuring the coordination or representative inclusion of local authorities. However, the following are members of the Conference: the mayor of the municipality if the territorial area of the local health authority coincides with that of the municipality, the president of the conference of mayors, or the mayor or district presidents if the territorial area of the local health authority is larger or smaller than the territory of the municipality, respectively; representatives of regional associations of local authorities." With specific reference to the composition of the Conference, it should be noted that there is a lack of uniformity in the regulations introduced at regional level, which differ in terms of the margin attributed to the representation of local or regional bodies. The different composition of the Conference is also reflected in its role: where it is open to the representation of local authorities, the latter will have the opportunity to discuss and develop common positions and requests to be presented to the Region; if, on the other hand, the composition of the Conference gives greater prominence to regional representation – through the participation of regional councilors for health and social policies – this forum will become the place where regional authorities listen to the requests of the bodies closest to citizens; on this point, see D. Paris, *Il ruolo delle regioni nell'erogazione dei servizi (The role of regions in the provision of services),* op. cit.; M. Cosulich, *The representation of local authorities. Conference or Council?,* in *The institutions of federalism,* 1, 2001.

[195] Pursuant to paragraph 2 *ter* of Article 2 of Legislative Decree 502 of 1992 (introduced by Legislative Decree 229 of 1999), "The draft regional health plan shall be submitted to the Conference referred to in paragraph 2 *bis* and shall be approved after examination of any comments

From a second perspective, the 1999 legislation appears to aim, in part, at reducing the role of regional authorities in the health sector, on the one hand, by providing for incisive powers of substitution for the Minister of Health[196], accompanied by stringent limits on regional health planning; the overall result of the reform is a strengthening of the central role in the organization and implementation of health care[197].

The 1999 legislation appears to depart from previous legislative trends aimed at strengthening the regional role in healthcare organization; however, this new legislation seems to move in the same direction insofar as it reformulates the relationship between the state and the regions by leveraging, on the one hand, the principle of subsidiarity and, on the other, their inclusion in public spending reserved for the National Health Service[198].

Although far from achieving a point of equilibrium in the difficult balance between the center and the territories in the field of healthcare, the attempts at reform in the

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made by the Conference. The Conference shall also participate, in the forms and manner established by regional law, in the verification of the implementation of the local implementation plan by the hospital trusts referred to in Article 4, and of the metropolitan implementation plans."

[196] Reference is made in particular to the provision of Article 2, paragraph 2-*octies*, of Legislative Decree 502 of 1992, which provides for the exercise of substitute powers by the Minister of Health after certain requirements have been met, such as: "after consulting the region concerned and the Regional Health Services Agency and setting a reasonable deadline for action," after which, "after hearing the opinion of the Agency and consulting the Permanent Conference for relations between the State, the regions, and the autonomous provinces of Trento and Bolzano, proposes to the Council of Ministers the substitute intervention, including in the form of the appointment of a commissioner ad acta." This procedure has been provided for in the cases expressly referred to in paragraph *2-octies* of Article 2, namely: in the event of failure to establish the Permanent Conference for Regional Health and Social-Health Planning, and failure to adopt the Local Implementation Plan and define the procedures for the participation of the local authorities concerned. Furthermore, the use of substitute powers is also provided for in the subsequent Article 19 ter, paragraph 3, letter d) of the same legislative decree, where this provision provides for the use of the powers referred to in paragraph *2-octies* of Article 2 in "cases of regional inaction in the adoption and implementation" of programs to reduce the regional health expenditure deficit.

[197] "The overall impression is that the government authority intends to maintain a central role in the system of division of powers and functions, in many cases even direct management, in the belief that only through a national control room is it possible to reduce the deficit and undertake a policy of spending restraint," according to C. Bottari, Il *diritto alla tutela della salute (The Right to Health Protection)*, in R. Nania, P. Ridola (ed.), I *diritti costituzionali,* Vol. II, Giappichelli, Turin, 2002.

[198] On this point, see R. Balduzzi, *Title V and Health Protection,* in R. Balduzzi, G. Di Gaspare (eds.), *Healthcare and Assistance after the Reform of Title V,* Giuffrè editore, 2002; in which, with regard to the provision of substitute powers introduced with the reforms of 1990, reference is made to "provisions which, on the one hand, significantly highlight the characteristics of the model known as concerted planning, which is based on solid planning choices, shared as much as possible by local authorities (...) and, on the other hand, they sought to respond to the possibility of shortcomings in the concrete provision of the benefits and services provided for in acts of concerted planning between the state and regional levels."

1990s constituted an important milestone. This conclusion can be corroborated by the decision, a few years later, to introduce many of the measures envisaged by these reforms—first and foremost the Essential Levels—into the constitutional reform.

It should be noted that the increase in the autonomy of the regions in the healthcare sector, although supported by the organizational principle of territoriality, seems to be attributable to another fundamental principle, not only of the National Health Service, but of the constitutional fabric itself.

The possible presence of partially different regional systems is in fact intended to respond to the need to adapt healthcare regulations to the specific circumstances of a particular territory, thus responding to the principle of universality and comprehensiveness of health protection[199], provided for by Law No. 833, finding its constitutional reference, from an organizational point of view, in the principle of subsidiarity and, from a substantive reading, it seems possible to identify as a reference also the principle of equality in its version of substantive equality referred to in Article 3, second paragraph, of the Constitution[200].

Therefore, even in the legislative framework, it is possible to identify an instrumental use of territorial articulation, aimed at adapting the organization and regulation of healthcare to the concrete needs of more limited territorial areas.

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[199] "The existence of the National Health Service, in fact, imposes a series of constraints that constitute a limiting objective to the provision of generalized and generic differentiations between regional health services. A national health protection system based on the universality of recipients, comprehensive healthcare coverage, equitable access in economic and territorial terms, appropriate services, and financing based on general taxation (progressive, i.e., equitable) has among its primary objectives that of promoting convergence between different regional situations, aiming to reduce territorial inequalities and the resulting disparities in personal treatment, not to crystallize them," according to R. Balduzzi, D. Servetti, *Differentiated Regionalism and Healthcare,* in *Rivista AIC,* 2, 2019.

[200] The constitutional importance of healthcare organization is affirmed by A. Napolitano, *The Multilevel Dimension of the Right to Health. Protection Requirements and System Constraints,* Editoriale scientifica, 2025, in which the author states that "The healthcare system (...) is therefore not simply a set of structures or services, but a coherent and purposeful legal-institutional system, supported by public planning aimed at pursuing the common good, and structured to ensure universality, equality, and equity in access to care."

2.2 Continued. The constitutional reform of 2001: the constitutionalization of Essential Levels

The regionalist spirit of the healthcare reforms of the 1990s culminated in the constitutional reform of 2001, which completely overhauled Title V of the Constitution concerning relations between the State and the Regions.

The reformist approach was to increase the regions' autonomy by reversing the Italian legal system's definition of the state as a regional state, emphasizing the two-dimensional nature of a "single and indivisible" republic, even though it is composed of territorial autonomies[201].

The 2001 reform not only implements what has been interpreted as the territorial expression of the pluralist principle that has permeated the Constitution since its inception, but also uses regionalism as a tool to rediscover the foundations of its democracy, with a view that sees the central state as the guarantor of constitutional rights and principles, in which the regions become the main legislative actors[202].

Although this model was believed to be successful precisely because of its primary regulatory precedent consisting of the decrees of the 1990s, which gave the healthcare system a regionalist character, when the reform is placed in a concrete context, it is possible to see how, *from the outset,* it had characteristics that meant the ambitious regionalist project could not achieve the desired outcome.

This difficulty in implementation, stemming from *the letter of the law*, also spilled over into the practical sphere, causing the failure or slow implementation of the numerous provisions introduced following the 2001 reform[203].

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[201] "The unity and indivisibility of the Republic are based on the recognition of the unity of the people, to whom Article 1, second paragraph, of the Constitution attributes sovereignty. The Constitution recognizes and guarantees pluralism (...) which is also reflected at the institutional level (Articles 5 and 114 of the Constitution)," according to Constitutional Court ruling no. 192 of 2024, legal opinion no. 4.

[202] On this point, see D. Paris, *The role of the regions in the organization of health and social services six years after the reform of Title V: division of powers and implementation of the principle of subsidiarity,* in *Le* Regioni, 6, 2007; G. Carpani, *Comment on Art. 2,* in F.A. Roversi Monaco (ed.), *The new national health service,* Rimini, 2000; G. Mor, *The new organizational structure of the National Health Service,* in *Public Health,* 6, 1997.

[203] "After the 2001 reform, the division of legislative powers between the State and the Regions appears to be marked by a gap between the abstract design and reality (...) while the text seems to outline a rigid division of powers, based on the logic of state and regional spheres of competence, practice has seen the establishment of a flexible division in which legislators (especially state legislators) can, at times and under certain conditions, venture into the opposite camp," according

It can therefore be said that the innovative scope of the 2001 reform of Italian regionalism has been mitigated, on the one hand, by the literal wording of certain regulatory provisions which, partly due to the jurisprudence of the Court, have often led to the centrality of the intervention of the state legislator[204]; and, on the other hand, by the slow – and sometimes even failed – implementation of some of the provisions introduced[205].

Following this necessary – albeit brief – introduction to the constitutional reform of 2001, in order to bring the discussion back to the topic of interest, we will analyze in greater detail the changes made by this reform to the health care system.

In the specific sector of health protection and healthcare organization, the Italian model had taken on such a form, particularly following the decrees of the 1990s, that it could be described as healthcare regionalism. The subsequent constitutional reform attempted to replicate this model in other sectors; however, the revised Title V did not merely transpose the changes made by primary legislation into the constitution, but also significantly redefined the relationship between sources of law and, above all, between regional authorities and the central government.

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to G. Di Cosimo, *Materie (riparto di competenze) [Subjects (division of powers)],* in *Digesto delle Discipline Pubblicistiche [Digest of Public Law], UTET;* with specific reference to the role of the Constitutional Court, see A. Morrone, *La Corte costituzionale riscrive il Titolo V? (Is the Constitutional Court rewriting Title V?),* op. cit.

[204] As highlighted by A. Pitino, *Autonomie e salute,* in A. Morelli, L. Trucco, *Il valore delle autonomie nell'epoca repubblicana,* Giappichelli, Turin, 2015; although health protection "is primarily a matter characterized by a particularly high level of institutional collaboration at various levels," such collaboration seems to stop at the level of "decisions most relevant to the National Health Service." In fact, the broad interpretation of the fundamental principles of public finance coordination "seems to have ushered in a new era of state centralism," aided by the climate of emergency that spread in the wake of the economic and financial crisis.

[205] For a complete historical reconstruction of Italian regionalism, from the discussion in the Constituent Assembly to the reforms implementing the so-called first regionalism, up to the analysis of the critical issues concerning the implementation of the 2001 reform, see L. Califano, I *nodi irrisolti del regionalismo italiano (The unresolved issues of Italian regionalism),* in *Cultura giuridica e diritto vivente (Legal culture and living law),* 10, 2022.

[205] It is worth noting the partial disharmony between the written Constitution and the living Constitution with regard to federalist ideology, which culminated in the reforms of the 1990s and the 2001 reform of Title V (Constitutional Law 3/2001), mitigated as a result of consistent constitutional jurisprudence, which identified the principles of loyal cooperation, territorial solidarity, unity, and indivisibility of the Republic as the fundamental cornerstones of the Italian State, thereby mitigating the innovative scope of the Reform. See G. M. Salerno, *Leale collaborazione,* in M. Cartabia and M. Ruotolo (eds.), *Enciclopedia del diritto. I Tematici, Potere e Costituzione,* Milan, Giuffrè, 2023; in which the author defines the principle of loyal cooperation as 'the crucial canon of interrelation and connection between the exercise of state powers and the exercise of regional powers', whose role and importance emerges significantly in the season of second regionalism (post-reform 3/2001), contributing to harmonizing the reformed constitutional framework in a sense of continuity with the previous one.

As it is not possible to dwell on the numerous changes, critical issues, and innovative aspects brought about by the 2001 reform, we will limit ourselves to analyzing the scope of the constitutional reform in the healthcare sector.

Given the particular importance attributed, since the beginning, to the regional role within the organizational structure of the national health service, the redefinition of legislative competence resulting from the constitutional reform could not fail to have important effects in the specific sector under discussion.

A first important change took place in the redefinition of the division of powers between the State and the Regions, in which, pursuant to the revised Article 117 of the Constitution, healthcare is included in a twofold sense: on the one hand, through the provision of concurrent competence for 'health protection' pursuant to Article 117, paragraph III of the Constitution; accompanied by the provision of exclusive state competence relating to the determination of the Essential Levels of services concerning social and political rights referred to in Article 117, paragraph II, letter m) of the Constitution[206].

Firstly, starting from an analysis of the concurrent jurisdiction of 'health protection', it seems appropriate to emphasize an important basic premise: in a 'reversed' division of powers that sees the residual clause in favor of the regional legislator, the areas of concurrent competence are characterized by the presence of a multiplicity of legislative actors such as the central state and the regions, whose legislative competence is bound by the definition of the fundamental principles of the matter determined by the state through legislation.

Therefore, beyond the symbolic value following the constitutionalization of regional competence in the field of health protection, the mechanism inherent in defining it as concurrent jurisdiction leaves the dynamics of healthcare legislation unchanged, which, as we have seen in the previous paragraph, had already been

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[206] On the possible interference of the exclusive state competence regarding the determination of essential levels of service (Art. 117, II lett. m Cost.) and the concurrent competence of health protection, see M. Di Folco, *The participation of territorial autonomies in the determination of essential levels in healthcare. Substantive and procedural profiles,* in R. Balduzzi (ed.), *Italian healthcare between essential levels of care, health protection and the* devolution *project*, Giuffrè editore; contrary opinion R. Bifulco, *Federalism and rights,* in T. Groppi (ed.), *The Republic of Autonomies,* Turin, 2001, according to whom this title of competence is only applicable to matters of residual regional competence and not to those falling within the list of concurrent competences.

established in the original 1978 reform and subsequently expanded following the corrective decrees of the 1990s[207].

What was innovative, rather, was the classification of the concurrent matter, which changed from 'health and hospital care' in the previous constitutional version to 'health protection' today; a concept which, although it cannot be said to correspond to the right referred to in the previous Article 32 of the Constitution, can nevertheless be said to be broader than the pre-reform version[208].

The reformulation of Article 117 of the Constitution allows us to reflect on the relationship between "health protection" and "healthcare organization" and, consequently, between the role reserved for the central government and that recognized for regional legislators.

The change in the title of competence inevitably has repercussions from an organizational point of view. Following the textual reformulation of the provision in Article 117 of the Constitution, the question arose as to whether the title of concurrent competence in the field of "health protection" included the previous "health and hospital care," or whether the latter constituted a title of residual regional competence.

However, following a clear constitutional jurisprudential development[209] , it is possible to affirm the absence of any real conceptual autonomy in the field of

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[207] Although the 'literal wording presents a certain discontinuity with the previous constitutional text, as was certainly the rationale behind the constitutional reform. the textual discontinuity is nevertheless probably greater than the 'substantive' discontinuity, so to speak, if it is considered in the light of constitutional legislation and case law on health matters, especially if one takes into account the evolution of the health system that took place particularly in the 1990s," according to N. Viceconte, L. Giachi, *Healthcare between the Constitution and case law interpretation,* in S. Mangiameli, A. Ferrara, F. Tuzi (eds.), *The division of powers in the Italian regional experience between public matters and policies,* Giuffrè, Milan, 2020; on this point, see also D. Morana, *Health Protection,* in G. Guzzetta, F.S. Marini, D. Morana (eds.), *Matters of Regional Competence. Commentary,* Naples, 2015; G. Carpani, D. Morana, *Legislative Powers in the Field of "Health Protection,"* in *Manual of Health Law,* Bologna, 2013; R. Balduzzi, D. Servetti (eds.), *The constitutional guarantee of the right to health and its implementation in the National Health Service,* in R. Balduzzi, G. Carpani (eds.), *Manual of Health Law,* Bologna 2013;

[208] Potentially suitable for covering various sectors in addition to those strictly related to healthcare organization, such as health protection in the workplace, health prevention methods, pharmaceuticals, care practices, and veterinary health on point C. Fasone, *Health protection (Art. 117. 3),* in R. Bifulco, A. Celotto (ed.), *The subjects of Art. 117 in constitutional jurisprudence after 2001,* Naples, 2005;

[209] Starting from judgment no. 386 of 2006 of the Constitutional Court, in which the Court expressly attributes healthcare organization to the concurrent matter of "health protection"; this position is also confirmed in the subsequent judgment no. 437 of 2005, and also in judgment no. 181 of 2006 C. cost., specifically relating to the possibility of assigning management positions in the National

healthcare organization, which falls within the scope of concurrent competence for "health protection"[210] .

Although there seems to be no doubt about the desire to 'strengthen' the regional role in healthcare, which has already been enshrined in ordinary legislation, in practice this strengthening has proved to be of less value than expected.

On the one hand, the very nature of concurrent jurisdiction has inevitably compromised the regional legislative role, which necessarily had to comply with the principles laid down by the state.

In addition, as already mentioned, there is a wide range of different matters under Article 117 that could potentially fall within the scope of health protection in the broadest sense; these are often classified as matters falling within the exclusive competence of the state and therefore capable of encroaching on the legislative space reserved for the regions in this area. Particular reference is made here, by way of example, to matters falling within the exclusive competence of the state, such as environmental protection, international prophylaxis, and the coordination of public finance; the latter is particularly used by the national legislator to justify measures aimed at regulating the health deficit and the rules governing the commissioning of the region in the event of a health deficit.

A further 'critical' element regarding the division of powers in the field of health protection is the particular importance in this sensitive area of the need for uniformity and consistency in the protection of this right. This requirement has also been explicitly recognized at the constitutional level through the provision of exclusive state jurisdiction over the determination of essential levels of services concerning social and political rights. In addition, this matter serves as justification for the use of the substitute powers provided for in Article 120 of the Constitution.

Health Service, this prerogative is attributed to the field of health protection, due to the 'close connection that (...) they have with the organization of the regional health service' (legal consideration point 4.1).

[210] "Where a constitutional right exists, such as the right to health, it necessarily follows that the legislative framework that in some way affects that subjective right is a fundamental principle of the corresponding concurrent matter. But this leads to the denial of any scope for regional regulation, even for procedural and organizational aspects: the fundamental constitutional principle absorbs every aspect of regulation, weakening the vertical division outlined in Article 117, paragraph 3, of the Constitution," according to D. Morana, *Health protection between state and regional competences: constitutional case law guidelines and new regulatory developments,* in Osservatorio AIC, 1, 2018.

The name chosen by the 2001 constitution leaves no doubt about the transposition of the LEA mechanism which, as noted in the previous paragraph, was introduced in the first corrective decree of 1992, even in sectors concerning rights other than health, with respect to which they share the necessary provision by the State that is potentially suitable for differentiation across the territory as a result of different regional legislation. Therefore, through the mechanism of Essential Levels, as in healthcare, the legislator takes care to guarantee the level of uniformity necessary to prevent differentiation from turning into inequality. A 'safety net' according to some, 'the enlightening solution'[211] according to others, which, to date, has not yet found a complete regulatory framework, despite the fact that, following the implementation law no. 86 of 2024[212] , the determination of the LEPs is identified as a necessary requirement for negotiations between the government and the region concerned in order to acquire additional and specific conditions of autonomy under the third paragraph of Article 116 of the Constitution, the fate of which remains uncertain to date.

2.2.1 Continued. Essential Levels of service: between uniformity and differentiation in the protection of rights.

It is worth noting the mechanism through which, first at the regulatory level and subsequently also included in constitutional provisions, the difficult balance typical of composite states between the requirements of equality and differentiation[213] has been achieved in the Italian legal system: the Essential Levels.

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[211] Thus M. Luciani, *Constitutional rights between the state and regions (with regard to Article 117(2)(m) of the Constitution,* in *Politica del diritto,* 3, 2002

[212] The centrality at the regulatory level in the implementation of Article 116(3) of the Constitution derives primarily from Article 1(791) et seq. of Law No. 197 of 2022 (State budget for the 2023 financial year and multi-year budget for the 2023-2025 three-year period). This legislation defines Essential Levels as *"the constitutionally necessary spending threshold that constitutes an insurmountable core for the provision of fundamental social services, to ensure the fair and transparent conduct of financial relations between the State and the* territorial *autonomies*" pursuant to Law No. 197 of 2022, Article 791.

[213] It is necessary to emphasize the essential link between the fundamental principle of Article 5 of the Constitution—in its dual version as guarantor of unity and indivisibility and also of territorial pluralism—and Article 3: "The relationship between Article 5 and Article 3 is among the most open to the evolution of the form of the State. The progressive strengthening of territorial autonomies,

As already mentioned, the essential levels of services first became positive law at the primary level and only subsequently became part of the Constitution[214] as a matter of exclusive state competence.

The relationship between LEP and LEA can be described in terms of genus and species, whereby the Essential Levels of Care constitute the implementation of the former in the field of health protection; in addition to their name, both share their raison d'être in the need to ensure the uniformity of certain types of services considered essential as "unifying features that substantiate the concept of social citizenship"[215].

The difficulty in defining the clause in the second paragraph of Article 117(m) has led to the development of a doctrine aimed at determining the meaning of the term 'essential'. To this end, three main approaches have developed chronologically: in the first phase, the definition of essentiality was closely related to the financial possibilities of the institution called upon to provide the services in question; a second approach linked the concept to *the amount* of services necessary to satisfy the needs of equity and well-being of the population; and, finally, the approach that has developed recently interprets the clause in Article 117, paragraph II, letter m) m) in a clearly subjective sense, attributing the adjective 'essential' to all those conditions necessary to satisfy the needs of the individual in question. This approach has the significant consequence of leaving a wide margin of discretion to the legislator[216] , which is limited by the role reserved for the Constitutional Court,

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especially in the event that these were to take on a federal structure, could jeopardize the objective of substantive equality," according to R. Bifulco, *Art. 5,* in R. Bifulco, A. Celotto, M. Olivetti (eds.), *Commentario alla Costituzione, vol. I,* UTET giuridica, Milan, 136 ff. on this point, see also G. Comazzetto, I *livelli essenziali delle prestazioni tra processi di differenziazione ed esigenze di uguaglianza,* Jovene editore, 2024.

[214] M. Luciani, *Constitutional rights between the State and the regions (with regard to Art. 117, paragraph 2, letter m),* op. cit.

[215] See L. Cuocolo, *Essential Levels of Care,* in R. Balduzzi (ed.), *Italian Healthcare between Essential Levels of Care, Health Protection, and* Devolution, *Conference Proceedings—Genoa, February 24, 2003,* Giuffrè editore; on this point, see also M. Luciani, *Essential Levels of Healthcare Services between the State and Regions,* in E. Catelani, G. F. Ferroni, M. C. Grisolia (eds.), *The Right to Health between Uniformity and Differentiation. A Comparison of Healthcare Organization Models,* Giappichelli publisher, Turin, 2011.

[216] See M. Atripaldi, *Right to health and essential levels of care,* in *federalismi.it,* 2017; on this point, see also L. Trucco, *Social rights and essential levels of services between legislative policies and the Constitutional Court,* in E. Cavasino, G. Scala, G. Verde (eds.), *Social Rights from Recognition to Guarantees: The Role of Case Law,* Proceedings of the Annual Conference of the Pisa Group, held on June 8-9, 2012, Trapani, Editoriale Scientifica, Naples, 2013.

where this choice is potentially subject to scrutiny as to its reasonableness and consistency.

An important role in the process of defining the contours of this matter has been assumed by the Constitutional Court, which, through a jurisprudential orientation that began a few years after the 2001 reform, has brought the matter of Essential Levels back into the category of jurisprudential creation of so-called cross-cutting matters[217].

As clearly defined in the first relevant ruling on the subject – judgment no. 282 of 2002 C. cost. - the cross-cutting nature does not pertain to 'matters in the strict sense, but to a state competence capable of covering all matters in respect of which the legislator itself must lay down the necessary rules to ensure that everyone, throughout the national territory, enjoys guaranteed services, as an essential content of those rights, without regional legislation being able to limit or condition them'[218]. This connotation gives rise to a relative concept of essentiality aimed at determining the services to be considered essential in each case on the basis of the interests actually involved, thus allowing for the mobility of the division of powers pursuant to Article 117 of the Constitution[219].

The Court expressly refers to contexts in which, due to their close connection with the protection and guarantee of fundamental rights, possible divergences linked to differentiated regional legislation inevitably conflict with the egalitarian and homogeneous protection necessary to ensure compliance, *first and foremost*, with the principle of equality and all constitutional provisions relating to rights. These are cases in which, in a situation of balance, the demands for differentiation

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[217] On this point, see judgments nos. 282 of 2002; 407 of 2002; 248 of 2006; 387 of 2007; 50 of 2008 C. cost.

[218] Judgment no. 282 of 2002 C. cost.; on the ruling, see A. D'Aloia, *Health protection, technical-scientific assessments, limits to regional autonomy. Notes on constitutional jurisprudence,* in L. Violini, (ed.), *Towards the decentralization of* welfare *policies*, cit., p. 19 ff.; A. Mangia, *Health protection and technical assessments: a limit to regionalism? Legislative discretion and technical assessments,* in L. Violini, (ed.), *Towards the decentralization of* welfare *policies*, cit., p. 51 ff.; D. Morana, *Detailed state regulations on health care between the old and new Title V: insights from constitutional jurisprudence,* in L. Violini, (ed.), *Towards the decentralization of* welfare *policies*, cit., p. 135 ff.

[219] Thus E. Pesaresi, *The 'determination of essential levels of service' and the subject of 'health protection': the indivisible projection of a unified concept of citizenship in the era of institutional decentralization,* in *Constitutional Jurisprudence,* 2, 2002.

and autonomy arising from different territorial situations must necessarily be considered recessive due to needs considered to be a priority.

In view of this potential interference by the state legislator in matters falling within regional competence, the Court has established the necessary regional participation[220] in the determination of Essential Levels, as this cannot be achieved unilaterally by the state legislator. Although the determination of Essential Levels falls within the exclusive legislative competence of the State, it can also affect regional competences precisely because of its cross-cutting nature.

The regional participation required is nothing more than compliance with the principle of loyal cooperation, which, in our regional system, is expressed through the involvement of the State-Regions Conference system in decision-making processes relating to matters of regional interest.

In view of this important indication by the Court and the definition of the procedure for determining the LEAs, at the time of writing, the legislator has not yet fulfilled its task of establishing the methods for determining the essential levels of services for a long period of time.

Since the constitutional reform, it has been necessary to wait until Budget Law No. 197 of 2022, which, after 21 years, is the first to provide for a sort of procedure for determining the Lep that partly follows the one already established for the Lea. However, the fate of this procedure, identified as a precursor to the implementation of so-called differentiated regionalism – introduced shortly thereafter with Law No. 86 of 2024 – is currently unclear. Pending the outcome of the doctrinal and jurisprudential debate on this point, which should provide us with more precise indications, we will limit ourselves here to briefly illustrating the procedure provided for by the 2022 law and how it was transposed into the subsequent 2024 law, as well as the latest amendments made by the Constitutional Court to this legislation.

Law No. 197 of 2022 establishes a Steering Committee[221] supported by the Commission for Standard Requirements and the Committee for the Definition of Lep in order to determine the content of the clause referred to in the second

[220] Sentences nos. 88 of 2003; 134 of 2006 C. cost.

[221] Pursuant to Article 1, paragraph 791 et seq. of Law No. 197 of 2022.

paragraph, letter m) of Article 117 of the Constitution[222]. This is followed by the implementation of the so-called differentiated regionalism provided for in the third paragraph of Article 116 of the Constitution.

A preliminary ruling issued at the regulatory level which, although suitable for translating into law the primary importance that the uniform protection of fundamental rights occupies within our constitutional system[223], does not in fact find the same success in practice.

In line with the conclusion of the CLEP's work[224], two critical considerations have been highlighted by legal scholars. The first is the excessive technicality used in the definition of the Lep, which is reflected in the second, represented by an excessive marginalization of the role of Parliament.

Starting from the principle, despite what has been said so far, the Essential Levels of Performance, according to the final conclusions of the Committee, seem to have lost the spirit of guarantee that defined them as a tool for the protection of fundamental rights, becoming instead administrative and financial tools[225]. This conclusion is also reflected in the choice of the instrument originally envisaged for this definition: namely, the Prime Ministerial Decree[226].

The use of this quasi-regulatory instrument appears to be at odds with the constitutional framework of the matter both in substantive terms, causing the Essential Levels of Services to become overly technical, reduced to mere financial compliance rather than an instrument for guaranteeing the protection of rights; and

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[222] On this point, see L. Violini, *Essential levels and differentiated regionalism: reflecting on the links between Article 117, paragraph II, letter m) and Article 116, paragraph III of the Constitution in light of the work of the CLEP,* in *federalismi.it,* 2024; V. Tondi delle Mura, *It's not Voltaire: the blank (and gray) pages of the 'Final Report' of the Committee for the Identification of Essential Levels of Performance,* in *federalismi.it,* 15/2024.

[223] A. D'Aloia, *Rights and Autonomous State,* in E. Bettinelli, F. Rigano (eds.), *The Reform of Title V of the Constitution and Constitutional Jurisprudence, proceedings of the Padua seminar held on June 6-7, 2003,* Giappichelli publisher, Turin, p. 80 ff.

[224] Technical-scientific committee with investigative functions for identifying essential levels of services, *Final report,* presented on October 30, 2023, by Prof. Sabino Cassese, in *federalismi.it,* no. 27/2023.

[225] See V. Tondi delle Mura, *LEPs on a roller coaster. Initial observations on the 'Final Report' of the Committee for the identification of essential levels of performance,* in *Nuove Autonomie,* 1/2024; M. Calamo Specchia, *Differentiated autonomy and inter-territorial solidarity: food for thought for a constitutionally sustainable reform?,* in *Rivista AIC,* 5/2023.

[226] For an in-depth study, see M. Rubechi, The *President's Decrees, Study on d.P.C.m., government regulations and decision-making dynamics,* Giappichelli publisher, Turin, 2022.

from a formal point of view, causing an imbalance in decision-making power, marginalizing the role of the Chambers and avoiding possible review by the Court. Although attempts were made during the parliamentary debate to remedy this discrepancy by requiring, in the version of the law currently in force, the use of the different instrument of legislative decree, for many this remedy proved to be merely apparent for two reasons: firstly, because legislative decrees, according to the amendment to the legislation, are intended exclusively *for the future,* without prejudice to the effects of the choices made through the previous Prime Ministerial Decrees[227], and, secondly, continues to reserve a central place for this administrative instrument, providing for its use for the purpose of updating the Lep previously defined by legislative decree[228].

The legislation in question has not been spared numerous criticisms raised by legal scholars and political forces, which cannot be analyzed here for reasons of space. Focusing on the two aforementioned points, it seems useful to analyze—albeit briefly—how the Council, called upon to judge the constitutional legitimacy of implementing law no. 86/2024, focused in particular.

In its recent ruling No. 192 of 2024, the Court addressed and amended the three key points[229] of Law No. 86 of 2024, bringing regionalism back from its divisive traits to a cooperative differentiation consistent with the form of state outlined in our Constitution. The Council ruled on points relating to the possibility of transferring entire matters to regional competences rather than specific functions, the marginalization of Parliament in the process of transferring functions and determining essential levels of performance, and, finally, the financial system designed to support differentiated autonomy.

Given the numerous issues addressed, I will limit myself to focusing, albeit briefly, on the main issue of this study: the dynamics of determining the essential levels of service within the context of the decision of the Constitutional Court.

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[227] Pursuant to Article 3, paragraph 9, Law No. 86/2024.

[228] Pursuant to Article 3, paragraph 7, Law No. 86/2024.

[229] Thus E. Cheli, *The form of the regional state in a historic ruling by the Constitutional Court,* in *astridonline.it,* 18/2024.

The issue is divided into two parts of the ruling, one concerning a purely formal analysis reserved for the type of source of law used, the other more substantial, referring to the definition and purpose of the ELPs themselves.

The dynamics concerning the sources of law used in the process of determining and updating the Essential Levels are traced back to the violation – first reported and subsequently ascertained – of Article 76 of the Constitution. Article 1 of the law under review, insofar as it establishes that the determination of the Lep must take place through one or more legislative decrees, was considered to lack the 'guiding principles and criteria' required by the Constitution, as these were considered to be determined by reference to the provisions of Article 1, paragraph 791 et seq. of Law No. 197 of 2022[230].

With regard to any modification and/or updating of the Essential Levels defined by legislative decree, the same law entrusts this activity to the different instrument of the Prime Ministerial Decree. This expedient was also rejected by the Council because it was considered not only illogical and[231] but also constitutionally illegitimate.

On the "substantive" side, regarding the nature and purpose of the Essential Levels, the Court starts from a fundamental ruling: namely, the difference between the Essential Levels of Care and the minimum core of rights[232]. While the latter is

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[230] Pursuant to Article 791 of Law No. 197 of 2022, "This paragraph (...) regulates the determination of the essential levels of services concerning civil and social rights that must be guaranteed throughout the national territory, (...) as a constitutionally necessary spending threshold that constitutes the minimum requirement for providing fundamental social services, ensuring fair and transparent financial relations between the State and regional authorities, and promoting the equitable and efficient allocation of resources linked to the National Recovery and Resilience Plan (...). The attribution of additional and specific conditions of autonomy referred to in Article 116, paragraph 3, of the Constitution relating to matters or areas of matters relating (...) to civil and social rights that must be guaranteed throughout the national territory, is permitted subject to the determination of the relevant essential levels of performance (LEP).

[231] *"Article 3, paragraph 1 (examined in point 9.2) confers legislative power for the determination of the LEPs. Article 3, paragraph 7, provides that these future legislative decrees may be amended by a sub-legislative act, i.e., by a Prime Ministerial Decree. This mechanism is highly contradictory and inconsistent with the system of sources (...) Article 3, paragraph 7, cannot have the force of legislative decrees determining the LEPs, because they do not yet exist. Therefore, the contested provision configures the Prime Ministerial Decree as a primary source, as it is empowered to amend a legislative decree by its own force. Article 3, paragraph 7, by contradictorily providing that a future act having the force of law may be amended by a sub-legislative act, violates Article 3 of the Constitution"* judgment no. 192 of 2024, legal consideration point 13.2 Constitutional Court.

[232] E. Pesaresi, *The 'determination of essential levels of services' and the subject of 'health protection': the indivisible projection of a unified concept of citizenship in the era of institutional decentralization,* op. cit. identifies the difference between the minimum level and the essential

a limit deriving directly from the constitutional text, the protection of which cannot be financially conditioned, the Essential Levels are the result of a balance, an expression of the political choice from which their determination derives: "a constraint for the regional legislator, taking into account the available resources"[233].

In line with the Court's indications, we can therefore analyze the implementing legislation in a different light, which seems to make the provisions contained therein more understandable, although still not exempt from criticism.
By ontologically distinguishing constitutional protection, guaranteed for the minimum core of rights, from that of the Essential Levels concerning civil and social rights, which the Court reserves for the Legislator, the Judge of Laws seems to support the choice to "index" the LEPs which, due to their intrinsic nature, are inevitably linked to economic factors.
However, this substantial distinction does not allow Parliament to be deprived of its natural role as a political decision-maker, since, according to the Judges themselves, 'the LEPs involve a delicate political choice, because it is fundamentally a question of balancing the equality of private individuals and regional autonomy, rights and financial needs, and also the different rights between them'[234].

According to the Court's indications, it therefore seems possible to say that, given the practical importance that makes the determination of LEPs a technical-financial decision-making process, this connotation cannot, in fact, translate into a complete outsourcing of the 'compromise role of Parliament'[235], as the political nature of the matter referred to in Article 117, second paragraph, letter m) of the Constitution – in that it presupposes a balance between rights and requirements of

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level of the right as a progression in the relative protection activity, linking the former to the object of protection of the Court, reiterating 'the semantic non-coincidence between minimum levels and essential levels, where the former would represent, as the minimum essential content of rights, a threshold that cannot be altered even by the national legislator, of which the Constitutional Court would be the supreme guardian. Beyond this threshold, the legislator may set essential levels, understood as a value greater than or equal to the minimum, as well as a moment of uniform definition of the common concept of citizenship, which in turn is unavailable to the regional legislator."

[233] Judgment no. 192/2024, legal consideration 14.1.

[234] Judgment no. 192/2023, legal consideration 9.2.

[235] V. Tondi delle Mura, I *LEP sulle montagne russe,* op. cit.

equal constitutional importance – can only be the result of work that finds its center of gravity in the parliamentary debate.

What the Court highlights is the loss of the finalistic significance that the determination of these levels was supposed to have in the implementation of the third paragraph of Article 116 of the Constitution. Although the administrative nature of this instrument has been recognized – given the essential financial link – it is considered necessary that the determination process remain within the Legislative Assembly, just as this process must be completed without losing sight of the purpose for which it was intended.

2.3 Continued. Recent challenges facing the Italian healthcare system: the 'Mission Six' of the NRP and the (possible) implementation of differentiated regionalism

The healthcare organizational structure, as articulated following numerous legislative interventions – as we have seen, both ordinary and following constitutional reform – is based on the integration of different levels of government, the result of a balance between the needs of protection and financial sustainability.

This difficult balance now seems to be facing further restructuring following the approval and adoption of the reforms provided for in the National Resilience Plan[236]. The Plan, which is part of a post-emergency context, is structured around a series of sectoral reforms, organized according to guidelines—known as pillars—identified at the EU level[237]. One of these sectors could only be health, identified in Mission Number Six of the Italian Plan.

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[236] The Italian PNRR finds its legal basis in EU Regulation 241/2020, which establishes the recovery and resilience mechanism, accompanied by the Guidelines drawn up by the EU Parliament and Council. EU legislation defines in detail the provisions and content of the Plans, which set out missions, general and specific objectives, the methods and criteria for the allocation of resources, and the achievement of targets and objectives through the preparation of a calendar of investments and reforms with a deadline of June 30, 2026. The Italian Plan was approved by the Commission and subsequently by the Council with Implementing Decision 2021/241.

[237] "The Plan proposal approved by the Commission and endorsed in the Implementing Decision therefore undoubtedly has prescriptive content and establishes legal obligations for the Member State," according to M. Cecchetti, cit. who speaks of an "asymmetrical contractual relationship" between the Member State and the Commission, which enjoys various prerogatives, the most significant of which are: the possibility of approving or rejecting a change to the Plan during its

Mission Health No. 6 of the Plan is structured in two parts: the reform of local healthcare, based on the strengthening of local networks and a restructuring of the local healthcare system[238], and, secondly, the implementation of the digitization of the national healthcare system[239].

For the purposes of this study, we will attempt to provide an analysis of the innovations proposed by the Plan with regard to the reform of local healthcare.

Healthcare reform is part of the various regional organizational models, in a scenario that can be described as uneven and fragmented[240]. The reform of local healthcare, which is regulated in detail and specifically in Decree No. 77 of 2022, provides for a reorganisation and reformulation of local networks and local medicine, which have already been the subject of attention by the legislator, whose previous intervention – although similar in some respects to that subsequently provided for in the Plan – was essentially aimed at responding to the needs of the last phase of the pandemic [241]. It seems useful to highlight the three guiding

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implementation only following a reasoned request based on objective circumstances; and the possibility of reducing the planned funding following any non-compliance. See on this subject N. Lupo, *THE National Recovery and Resilience Plan (PNRR) and some research perspectives for constitutionalists,* in *federalismi.it,* 1/2022; F. Polacchini, The *impact of the PNRR on the form of government and political processes,* in *Forum di Quaderni Costituzionali,* 4, 2022, 234.

[238] In particular, M6C1 of the PNRR aims to strengthen the services provided throughout the country through a total investment of €7 billion, broken down as follows: €2 billion for the construction of 1,288 community homes and personal care; €4 billion to make the home the primary place of care; €1 billion to strengthen intermediate healthcare and community hospitals.

[239] The second component of Mission 6, 'Innovation, research, and digitization of the health service', focuses on the technological and digital modernization of the National Health Service (SSN). Specifically, it includes the Electronic Health Record (FSE), the digitization of healthcare facilities, and the improvement of information systems for monitoring Essential Levels of Care (LEA).

[240] T. Andreani, *The National Health Service, between history and current events: reflections on the gestation and prospects for the implementation of territorial healthcare reform,* in *BioLaw Journal,* 3, 2023.

[241] The regulation of proximity networks is also developed in the so-called Relaunch Decree, Decree Law 34 of 2020. The third paragraph of Article 1 of the decree stipulated that 'healthcare companies, through the districts, shall implement integrated home care or equivalent activities for patients in isolation, including those housed in facilities (...) ensuring adequate healthcare support for the monitoring and care of patients'; and the following fourth paragraph, referring to the regions and autonomous provinces, required the latter to guarantee 'the highest level of care compatible with public health and safety requirements for infected individuals (...) as well as the protection of vulnerable people whose condition is aggravated by the current emergency, if they have not already done so, by increasing and directing therapeutic and care actions at home'; on the differences between Decree Law 34/2020 and the measures provided for in M6C1 PNRR, see E. Rossi, *Le Case della comunità del PNRR: alcune considerazioni su un'innovazione che merita di essere valorizzata (The Community Houses of the PNRR: some considerations on an innovation that deserves to be promoted),* in *Corti Supreme e Salute,* 2, 2021.

principles of this reform: the strengthening of home care, the development of telemedicine, and the adoption of an integrated social and health care approach.

The renewed territorial healthcare organization is rooted in the presence of healthcare districts. From a purely organizational point of view, it is identified as a "functional organizational structure of the ASL" (Local Health Authority), as well as a "privileged place for functional and organizational management and coordination dedicated to pursuing integration between the various healthcare structures, in order to ensure a coordinated and continuous response to the needs of the population"[242].

The structure outlined in the decree is then organized through the provision of so-called community homes[243], the central hub of the network of services under the direction of the District, identified as "an organizational model that provides concrete local assistance to the population of reference" as well as a coordination center responsible for social and health integration, being identified as an "integrated and multidisciplinary" workplace for all professionals involved in the planning and delivery of healthcare and social integration interventions.

The picture is completed by the provisions for community hospitals, a genuine healthcare facility for hospitalization and care, aimed at performing an "intermediate function between home and hospital admission"; whose target audience is identified as patients who need low-intensity healthcare interventions, thus preventing the improper use of the hospital network and promoting safe discharges[244].

One of the stated aims of this reform is to attempt to reduce the differences between the various regional healthcare systems, whose inconsistencies are the main cause of healthcare mobility between regions due to the type or quality of the services they offer.

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[242] Annex 1 to Ministerial Decree 77 of 2022.

[243] 'An easily identifiable physical location that citizens can access for healthcare and social-healthcare needs'.

[244] "Citizens of less prosperous southern regions are more than twice as likely to report unmet medical needs than those in wealthier northern regions, due to financial reasons, waiting times, or travel distances," according to the EuroHealth Consumer Index Report, compiled by Health Consumer PowerHouse Ltd (HCP) with the support of the European Commission.

The complex and integrated set of functions described above appears to be uniformly ensured throughout the country thanks to the widespread adoption of the organizational model in question. Faced with a highly centralized coordination that has a precise institutional location in the Ministry of Health, the implementation of the reform plan is effectively left to the Regions, which are called upon to operate within limited margins of organizational autonomy, expressed through the choice between a range of services not indicated as mandatory by government regulations[245].

In light of a more comprehensive analysis of the regulatory and institutional dynamics relating to the National Recovery and Resilience Plan, it is possible to speak of a purely executive and[246] loyal collaboration to describe the relationship between the central government and the regions, which can be seen in the development and implementation of the planned reforms[247].

The structural tension between uniformity and territorial autonomy translates into highly centralized governance in the hands of the executive; in this context, the regions and local authorities are identified as implementing bodies. This solution, which is controversial in some respects, is justified by systemic requirements—such as the reorganization of the healthcare system—as well as political and institutional requirements—arising essentially from the constraints imposed by the EU for the financing of reform plans[248].

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[245] Thus T. Andreani, *Il Servizio sanitario nazionale tra storia e attualità (The National Health Service between history and current events),* op. cit.

[246] Thus A. Dirri, *Loyal cooperation in the adjustment of the PNRR: an 'executive' regionalism to overcome territorial disparities,* in *Rivista AIC, 1*, 2024; on the regional role in the PNRR, see G. Falcon, *Journey to the center of the PNRR,* in *Le Regioni,* 4, 2021; C. Colapietro, *The Italian form of state and government put to the test by the National Recovery and Resilience Plan,* in *Rivista AIC,* 3, 2022; E. Catelani, *The PNRR and the constitutional order: an introduction,* in *Rivista AIC, 3*, 2022.

[247] Article 9 of Decree Law No. 77 of 2021 "The central administrations, the regions, the autonomous provinces of Trento and Bolzano, and local authorities shall be responsible for the operational implementation of the measures provided for in the PNRR, on the basis of their specific institutional competences"; According to Article 9 of the decree, in fact, the role of the regions must be carried out on the basis of what is already provided for in the PNRR and is particularly relevant in the implementation phase following the coordination and planning phase, as the regions are asked to complete measures that are the result of guidelines included in the Plan (...)" according to M. Trapani, *The conference system and halved regionalism: the difficult relationship between the PNRR and the regions in light of recent regulatory developments,* in *Rivista AIC,* 4/2021.

[248] The term 'European conditionality' is used to describe the conditionality that the legislation relating to the National Plan has with respect to the EU which, as already briefly mentioned, is manifested not only in the provisions contained in the relevant EU legislation – such as Regulation 241/2021 – but also through precise and specific monitoring or sanctioning powers granted to the

The entirely centralist solution that emerges from the regulatory framework relating to the Plan reaches its peak in the re-emergence of a narrative prior to 2001, attributable to the provision of broad substitute powers to the Government[249] and the positivization of the national interest[250].

Although in some respects this choice can be said to be justified[251] and supported by the previous pandemic management system[252], it cannot be said to be free from criticism. These emerge with particular vehemence when considering, from an initial point of view, the overall nature of the PNRR interventions which,

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Commission in the event of non-compliance with the provisions of EU legislation. The center is, of course, responsible for the entire operation: responsible, first and foremost, to the national community, since borrowing and significantly increasing public debt is no joke (...), and secondly, to the European Union, both in relation to the loan and – even more so – to the non-repayable grants," according to G. Falcon, *Viaggio al centro del PNRR (Journey to the center of the PNRR),* in *Le Regioni,* 4/2021.

[249] Although the terms of the legislation seem to designate the regions as the implementing bodies for the measures in the Plan, even in this context, the centrality of the executive is evident in all its preponderance. This occurs, in the context of implementation procedures, through the provision of Article 12 of Decree Law 77/2021, which, more than others, seems likely to have repercussions on compliance with constitutional provisions relating to the relationship between the State and the regions, introducing (the additional) possibility for the central State to replace these implementing bodies in cases of non-compliance, delays, or non-compliance with the provisions. The power of substitution provided for by the legislation is subject to the necessary assignment of a deadline of thirty days to the implementing entity by the Prime Minister – on the proposal of the Steering Committee or the competent Minister – at the end of which a commissioner ad acta is to be appointed, with the necessary powers to put an end to the non-compliance. Article 12, paragraph 1, Decree Law 77/2021 "In the event of continued inaction, on the proposal of the President of the Council of Ministers or the competent Minister, after consulting the implementing entity, the Council of Ministers shall identify the administration, body, organ, or office, or alternatively appoint one or more acting commissioners, to whom it shall assign, by way of substitution, the power to adopt the necessary measures or to ensure the implementation of the projects (...)'.

[250] It is the second paragraph of Article 1 of the decree that establishes the national interest as "pre-eminent" for the purposes of the decree and its implementation. A national interest which, although specifically relating to "the prompt and timely implementation of the measures" constituting the Plan, included in the same provision that brings its governance back to matters - cross-cutting - falling within the exclusive competence of the State, returns a narrative aimed at justifying a management that replicates, even in its implementation, a pattern of intervention in which the Government confirms its role as the undisputed protagonist, once again to the detriment of the Autonomies.

[251] G. Razzano, *PNRR: primary care, between opportunities for a "formative transition" and political and* administrative *unity*, in *Corti Supreme e* Salute, 2, 2022; in which the author proposes an interpretation of the overall structure of the PNRR 'as a way of taking seriously not only Article 5 of the Constitution, in its overall meaning, but also Article 95 of the Constitution, according to which the Prime Minister 'directs the national policy of the Government and is responsible for it. He maintains political and administrative unity, promoting and coordinating the activities of ministers"; on this point, see also M. A. Sandulli, *Healthcare, general enabling measures on simplification and justice in the PNRR,* in *federalismi.it,* 2021.

[252] On the regulatory management of the pandemic between the different levels of government*, see* Chapter IV.

although supported by the need for uniformity – as in the case of the reform of territorial healthcare – are part of a more complex plan, which includes missions such as territorial and social cohesion, as well as the reduction of the gaps between the north and south of the country; with regard to which it seems essential to ensure a margin of decision-making at the territorial level. Secondly, the 'centralist' solution adopted for the management of the interventions provided for in the Plan seems particularly dystopian when viewed in the current political and institutional context, in which the issue of differentiated autonomy still occupies a privileged position in the debate on Italian regionalism[253].

Although the issue of the implementation of regional autonomy seems to be once again, at the time of writing, in a state of 'stalemate' following the ruling of the Constitutional Court[254], which, dealing with the legitimacy of the law aimed at implementing it - Law No. 86/2024[255] - has profoundly reshaped its content, referring the matter back to the legislator.

However, it seems appropriate to at least briefly mention the possible impact that such implementation may have in the specific healthcare context.

Although, as demonstrated in the previous paragraphs, the healthcare issue has traditionally been intertwined with the evolution of Italian regionalism, the specific discussion around the theme of differentiated regionalism still seems to be a topic of considerable debate today.

The balance between uniformity and differentiation has found a meeting point in the establishment of regional healthcare systems, which are partially divergent from each other, although they are established within the unified framework defined by the National Health Service. However, the provision of Article 11 of Law No. 86 of 2024 seems to be a harbinger of complexities yet to be resolved insofar as it

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[253] A. Ruggeri, *Territorial autonomy today, from the point of view of constitutional theory,* in *Diritti Regionali,* 1/2024; on the fundamental principle of territorial pluralism, see also L. Califano, The *unresolved issues of Italian regionalism,* in *Cultura giuridica e diritto vivente,* 10/2022.

[254] Constitutional Court ruling no. 192 of 2024;

[255] On this topic, see G. Caporali, *The framework law on differentiated autonomy: an analysis of critical issues and prospects,* in *Italian papers on federalism,* 3/2024; G.M. Salerno, *Differentiated autonomy: constitutional problem or prospect?,* in *federalismi.it,* 19/2023; G. Guzzetta, *Potential, risks, and expectations of differentiated autonomy,* in *Nuove Autonomie,* 1/2024; S. Staiano, *Saving regionalism from disruptive differentiation,* in *federalismi.it,* 7/2023; L. Castelli, *Outstanding issues in the implementation of Article 116, paragraph 3, of the Constitution,* in *Diritti regionali,* 3/2023.

allows the dialogue established between the government and the regions concerned to continue, based on the draft agreements drawn up prior to the entry into force of this legislation.

With reference to the agreements presented by the regions of Lombardy, Emilia Romagna, and Veneto, which contain requests relating to healthcare, it is possible to note three aspects of convergence in terms of content that raise doubts about the possible unity of the system as previously outlined[256]. The most significant issue seems to be once again that linked to the possible establishment of supplementary forms of financing for the Regional Health Services (SSR), through the provision of supplementary healthcare funds that could potentially introduce disparities between the services offered in the territory[257]. This critical issue is accompanied by that relating to the differences that could arise as a result of the differentiated management of intramural private practice[258] and the organization of specialization schools, which would allow for differentiated treatment in terms of collective bargaining on the one hand, and, on the other, a different structure of employment prospects for new graduates[259].

Even though the discretion of the agreements implementing the provision of the third paragraph of Article 116 of the Constitution is limited by a series of constitutional constraints consisting of the state regulations governing matters of concurrent competence – including health – to which are added the fundamental

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[256] On this point, E. Catelani, *New requests for differentiated autonomy pursuant to Article 116, paragraph 3, of the Constitution: procedural aspects of dubious legitimacy and possible violation of rights,* in www.osservatoriosullefonti.it, *1, 2018; V.* P. Grossi, *The continuing relevance of differentiated regionalism. An analysis of the contents of the draft agreements,* in *Regional Rights,* 2, 2021.

[257] A. Napolitano, *The multilevel protection of health,* op. cit. "Regional requests for greater autonomy in terms of sharing healthcare costs, inextricably linked to the issue of supplementary healthcare funds, would in fact legitimize the regions concerned to set up substitute healthcare funds, including services included and not included in the LEA (Essential Levels of Care), risking a significant increase in overall healthcare spending and accentuating inequalities in access to care";

[258] On this point, Constitutional Court ruling no. 54 of 2015 indicates that the regulation of the private practice of doctors in the National Health Service "is one of the most characteristic elements in the regulation of the relationship between healthcare personnel and users of the Health Service, as well as of the healthcare organization itself" because 'the identification of persons entitled to practise private practice within the healthcare system (...) requires uniform regulation throughout the national territory';

[259] Articles 1 and 2 of the Health Annex to the Preliminary Agreement concerning the agreement provided for in Article 116(3) of the Constitution between the Government of the Republic and the Veneto Region; Article 1 of the Health Annexes to the Preliminary Agreements signed by the Government with the Lombardy Region;

principles of the Constitution that outline the form of state of our legal system; the uniformity in the protection of a fundamental right appears to be susceptible to compromise. [260]

According to others, however, the possible differentiation of regional regulations relating to certain functions may herald a new season of economic and institutional recovery, a positive experience that "would allow the regions to perceive the needs of their respective communities with greater awareness"[261].
A 'revitalisation of regionalism' in contrast to the centripetal trend that sees the Executive increasingly as the protagonist of important legislative policies.
In the face of numerous concerns that are still far from being resolved, it is believed that the dynamics relating to the Italian regional landscape are still evolving; indeed, it cannot be said to be necessary to focus attention on the regulatory and institutional dynamics relating to important situations such as the management of the PNRR, which seem to be moving away from situations of increased regional autonomy, especially in situations where the protection and effectiveness of fundamental rights such as the right to health are being discussed.

3. *The Spanish legal system: reasons for comparison.*

An analysis of the Spanish legal system, particularly with regard to healthcare organization, seems useful in providing valuable insights into the relationship between the substantive protection of rights and organizational structure. Given the numerous similarities between the Italian and Spanish legal systems, which in fact differ in one fundamental aspect relevant to the subject of this research: namely, the way in which relations between the central state and local authorities are structured.

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[260] R. Balduzzi, D. Servetti, *Differentiated Regionalism and Healthcare,* in *Rivista AIC,* 2019; refer to the "destruction of the National Health System" following an "increase in inequalities and inequities, without any perceptible advantages in terms of health protection and guarantee of Essential Levels of Care (LEA)"; 'the primary purpose of a national health protection system', the authors argue, 'is to reduce inequalities between territories and between people, so that the unity of the system (...) corresponds to an interest that cannot be derogated from by the procedure referred to in Article 116(3) of the Constitution'.
[261] Thus L. Chieffi, *The protection of the right to health between perspectives of differentiated regionalism and persistent territorial disparities,* in *Nomos le attualità del diritto,* 1, 2020;

Faced with an uncertain regionalism with blurred contours that fails to take a clear direction, such as that of Italy[262], a reading of the Spanish Constitution seems to define a model of autonomous state[263] in which the Autonomous Communities acquire full centrality in various aspects of public policy.

Before analyzing health protection in the Spanish legal system, it is useful to briefly outline this model of state, so that readers can understand the context in which this substantial and organizational protection is implemented and the specific features of this legislation.

It is necessary to start from the provisions of Article 2 of the Spanish Constitution (hereinafter referred to as C.E.), which establishes the principle of autonomy, without actually listing the constituent elements of this constitutional design. Contrary to what happens in the Italian text[264], the provision merely recognizes the concept of autonomy[265], leaving the communities free – within certain limits – to establish themselves as autonomous entities[266].

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[262] Reference is made in particular to the numerous attempts at reform that have taken place throughout Italian constitutional history in the context of structuring a regional model; in particular, following the constitutional reform of 2001, the attempt in 2006 and that in 2016 with the Renzi-Boschi reform; often these attempts at reform are opposed to each other; According to some legal scholars, one of the main problems with Italian regionalism is precisely the total absence of a unified plan, as highlighted by A. Barbera, *the 'original sin' of the regions,* in R. Bin (ed.)*, Il futuro delle regioni (The Future of the Regions*), Editoriale Scientifica, Naples, 2023.

[263] It should be noted that Spanish doctrine on the definition of "Estados de las Autonomias" is not unanimous; some authors refer to a federalist model, others favor the recognition of a model of "transition to federalism," while still others simply note its hybrid nature, as in M. Manganaro, *L'evoluzione del regionalismo differenziato alla luce delle riforme costituzionali (The evolution of differentiated regionalism in light of constitutional reforms). Some observations on this point, in comparison with the territorial model in force in Spain,* in *consultaonline,* 3, 2016; on Spanish regionalism, see J. Ruiperez Alamillo, *Sobre la naturaleza del Estado de las Autonomias,* in *Revista de Estudios Politicos,* 81/1993; T. Font y Llovet, *The process of 'federalization' in Spain: administrative organization,* in *Ist. Federalismo,* 1, 2000; R. L. Blanco Valdes, *Los rostros del federalismo,* Madrid, 2012; E. Aja, *Estado autonomico y reforma federal,* Madrid, 2014.

[264] Reference is made here to Article 114 of the Italian Constitution, which establishes that "The Republic is composed of the Municipalities, the Provinces, the Metropolitan Cities, the Regions, and the State," identifying through a closed list the entities that make up the Republic, as well as Article 131 of the Constitution.

[265] Article 2 of the Spanish Constitution: *"The Constitution is based on the indissoluble unity of the Spanish Nation, the common and indivisible homeland of all Spaniards, and recognizes and guarantees the right to autonomy of the nationalities and regions that comprise it and solidarity among them all*."

[266] The Spanish state model as outlined in the 1978 Constitution was not deliberately defined by the Constituent Assembly as a specific form of vertical state; rather, vague and open formulations were favored in order to allow the state itself to evolve according to multiple future scenarios. What emerges clearly is the desire to bring "all the autonomist concepts" that proliferated during the Franco period "under a single formulation"; on this point, see C. Buzzachi, *Uniformità e differenziazione nel sistema delle autonomie (Uniformity and Differentiation in the System of*

The relationship between unity-indivisibility and territorial autonomy in the Spanish legal system is more favorable to the autonomy of the individual territories that make up the nation: in this sense, broad statutory autonomy is recognized, through which individual communities are granted the power to assign themselves their own margin of autonomy, within the limits set by the Constitution[267].

With the reforms of the Statutes of Autonomy in 1994, the process of 'leveling of powers'[268] can be said to have been completed following the transfer of powers in the areas of health and education to the various C.C.A.A.[269].

Considering the specific subject of the research, it can be said that, despite the current constitutional framework that characterizes the Spanish autonomous system, healthcare regulations are not limited to the provisions contained in the various Statutes.

Both at the constitutional and regulatory levels, there is a need to ensure homogeneity and equality in the enjoyment of a right such as the right to health; these requirements are translated into regulatory provisions in which the role of the state legislator takes on great prominence, to the detriment of the autonomy granted to each autonomous community.

The following analysis will therefore attempt to provide a broader understanding of how the relationship between uniformity and differentiation is structured in a unique autonomous state, as well as to provide valuable insights into the organizational structure necessary to effectively protect the right to health.

Autonomies), Milan, 2003; according to which the realization of the vertical form of the state is not explicitly recognized in the constitutional text, which contains opening clauses that have allowed for the self-determination of the territories.

[267] In this sense, there are two ways in which autonomous communities can assume autonomy, the extent of which depends on the procedure to be undertaken. On the one hand, there is the 'fast' procedure referred to in Article 151 of the Spanish Constitution, which offers the possibility of obtaining greater autonomy, accompanied by the 'slow' procedure referred to in Article 143 of the Spanish Constitution, which is only possible five years after the entry into force of the 1978 Constitution and whose autonomy can only be requested in relation to the matters provided for in Article 148 EC.

[268] Thus M. Manganaro, *The evolution of differentiated regionalism in light of constitutional reforms. Some observations on this point, in comparison with the territorial model in force in Spain,* op. cit.

[269] On this point, see M. H. Rodriguez De Minon, *Asymmetric federalism: the Spanish case,* in B. Caravita (ed.), *Regions in Europe. A comparison of constitutional experiences. Austria, Belgium, France, Germany, Great Britain, Italy, Poland, Spain, and Switzerland,* Rome, 2002.

3.1 Health protection in Spain: right or principle

Any analysis of the health regulations implemented in the Spanish legal system must begin with a study of the provisions reserved for it in the 1978 Constitution. It seems necessary to start from an important basic premise: the right to health is not explicitly recognized in the Spanish Constitution, but its regulation can indeed be found in a multitude of provisions contained therein.

However, it is the provision of Article 43 that provides the most comprehensive regulation, identifying the right to health as a "guiding principle of social and economic policy"[270].

Even at first glance, it seems clear that the placement of this provision has implications both in terms of the substantive protection of the right to health, recognized as such in the first paragraph of the article ("The right to health protection is recognized ') and in terms of its organizational dimension[271], since the following paragraph recognizes the specific role reserved for the legislator in determining the organization of health care ('it is the responsibility of the public authorities to organize and protect public health'[272]).

The nature of the guiding principle emerges, in particular, when reading Article 43 in conjunction with Article 53[273]. According to the most traditional Spanish

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[270] Regarding the decision to include the right to health among the principles, S. Basile states that "It is not at all rational to include the right to health here because nothing in the economic system prevents the guarantee of a genuine right in this regard by a dedicated public health service, just as the right to education is guaranteed," in S. Basile, *Valori superiori,* E. García de Enterría, A. Predrieri (edited by), *La Costituzione spagnola del 1978,* Giuffrè editore, Milan, 1981.

[271] According to some, Article 43 of the Spanish Constitution does not allow for the identification of a positive right to receive treatment for specific individuals, but rather a sort of negative right, coinciding with "the right to be protected from any person or entity potentially responsible for damage to life and physical and moral integrity within the meaning of Article 15 of the EC Treaty." The second paragraph of the same provision provides for the obligation on the part of public authorities to organize and protect public health, "a phrase with implications in terms of public health" (according to S.R. Vinceti, *La tutela della salute nelle democrazie stabilizzate [The protection of health in stable democracies],* Giappichelli, 2024).

[272] ex co. 2 art. 43 EC "It is the responsibility of the public authorities to organize and protect public health through preventive measures and the necessary benefits and services. The law shall establish the rights and duties of all in this regard."

[273] He believes that the absence of the fundamental nature of the right to health emerges clearly from a combined reading of Articles 43 and 53 EC. M. L. Alonso, *La proteccion constitucional de la salud,* La Ley, Wolters Kluwer, Madrid, 2009; according to the author, applying the formal criterion derived from Article 53.1 EC, it follows that Article 43 does not have the nature of a fundamental right in this regard. In fact, by defining the rights included in Title II, Chapter II, "Rights and

doctrine, the provision of Article 43, considered in isolation, would constitute nothing more than a rule of action addressed to the public authorities with a view to providing services aimed at protecting health[274]. The total absence of a subjective dimension is not without implications, since the failure to recognize the nature of a fundamental right results in the impossibility of protection before the courts by citizens [275].

However, following a more careful and advanced reading, part of the doctrine has emphasized what is defined as the "expansive force" of Article 43. Based on a combined reading of this provision with others in the Spanish text, it is possible to affirm that the right to health is not entirely devoid of a subjective configuration.

Unlike the Italian legal system, which explicitly recognizes it[276], the nature of the fundamental right of the individual emerges following an integrated reading with other constitutional precepts, in particular that of Article 15 of the Spanish Constitution, i.e., the provision that establishes the right to life and physical and moral integrity[277]. A reading of the two provisions reveals a legal situation that is advantageous to the holder of the right and can be immediately enforced directly

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Freedoms," of the Title "Rights and Duties" as fundamental, Article 53 would, according to a purely formal approach, exclude all rights not included in the aforementioned section.

[274] This interpretation is also confirmed by Judgment No. 36 of 1991, FJ 5°, Constitutional Court, which states that "*the principles recognized in Chapter III of Title I, although they must guide the actions of public authorities, do not in themselves generate legally enforceable rights*."

[275] M. Garrido Falla, *Article 43,* in *Comentario a la Constitución,* Civitas, Madrid, 1980; according to which "It would be a simple rule of action, not enforceable before the courts, which requires public authorities to organize adequate services to protect health." On the direct constitutional justiciability of fundamental rights in Spain, see U. Adamo, *Constitutional protection in Spain: past, present, and future of direct appeals to the constitutional court between the subjective and objective nature of control,* in *Consulta online,* 3, 2015.

[276] *"On the other hand, the impact on the fundamental nature of the right to health, for example, in the case of the Italian Constitution and doctrine, has even led to an unfortunate and distorted comparative translation in Spain, which has ended up leaning mostly towards its non-'fundamental' nature (as it is located among the so-called 'guiding principles of social and economic policy') through this dogmatic-formalist approach, which has lost sight of the different systems of constitutional protection of fundamental rights in Italy and* Spain"; L. Quesada, op. cit.

[277] *The connections between Article 43 EC and other constitutional provisions (15, 40, 39, 41, 49, 50, 51, 45, 47) are only intended to illustrate the broad constitutional concept of health, and should not lead us to an erroneous perception of protection. Indeed, it cannot be obsessively redirected to the subsidiary and restrictive route of the right to protection through basically civil and political rights but, on the contrary, to the enjoyment of the highest possible level of health promoted by internal regulatory development*," according to L. J. Quesada, *Article 43,* in *Commentary on the Spanish Constitution, 40th anniversary 1978-2018,* Tirant lo blanch, Valencia, 2018, 829 ff.

before the courts without the intervention of the legislator[278] , which translates into the traditional positive and negative two-dimensionality of the right to health[279].

Added to this subjective situation is that which arises from a combined reading of the first and second paragraphs of the same Article 43 EC, from which derives the right to healthcare, as a genuine right to benefits. The right to healthcare, understood in this way, is realized through the legislation establishing the Spanish National Health Service, which is the means by which each individual has the opportunity to develop freely and with dignity within a social community[280].

In light of the brief reflections made so far, it is therefore possible to say that, at first glance, it may seem that the Spanish constitutional regulation of the right to health is reduced to a programmatic dimension. It is a guiding principle aimed at the legislator, who must pay specific attention to issues relating to health protection in the course of legislative activity.

Following a systematic reading of the various provisions contained in the Charter, as well as a reading of the provision in its overall meaning, it emerges that, in reality, the right to health is considered a fundamental right, read in conjunction with the right to life and physical integrity, from which derives its full judicial protection provided for by the Constitution; as well as a social right to benefits that necessarily requires the intervention of the legislator in order to be satisfied.

The realization of the right to healthcare—which is recognized in the text—will, however, take place a few years after the Constitution comes into force, with the establishment of the Spanish National Health System in 1986.

3.2 Division of powers in the field of healthcare

Moving on from a substantive analysis of the right to health and shifting our attention to the healthcare organizational model, we can see that this area is also

[278] M. L. Alonso, *La proteccion Consitucional de la salud,* cit.
[279] Reference is made here to the positive dimension, which consists in the right of the holder of the right to demand that other subjects—public or private—refrain from causing damage or alteration to the state of mental and physical integrity that constitutes human health; and to the negative dimension, meaning the moral and physical inviolability of the person.
[280] Ibid.

explicitly referred to in the Spanish Constitution, in the provisions defining the division of powers between the central government and the autonomous communities.

Before analyzing competences in the health sector, it is therefore necessary to review, without claiming to be exhaustive, the constitutional features that most characterize the Spanish regional model.

The division of powers is outlined in Articles 148 and 149 of the Spanish Constitution, which, included in Title VIII, contribute to determining a model of state characterized by regionalism with well-defined features.

Article 148, in fact, regulates the matters falling within the competences of the Autonomous Communities in its first paragraph, followed in the second by an express indication of the possibility that this list may be extended, within the framework of the reforms of each Statute of the respective Autonomous Community, while maintaining strict compliance with the limits of the following Article 149 Const, and within five years of the entry into force of the Constitution itself[281].

The following article, in fact, defines, through a copious list of thirty-two titles, the matters falling within the exclusive competence of the State. The last paragraph of the provision referred to in Article 149 deserves particular attention, as it constitutes the cornerstone on which the system of relations between the State and local authorities in Spain is based; after a more careful reading of the provision in question, it seems possible to identify a so-called double residual clause[282]. This provision not only establishes that matters not included in the list of exclusive state powers correspond to the Autonomous Communities, by virtue of the provisions contained in their respective Statutes; but the wording of the provision in question

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[281] Ex co 2 art. 148 C. E. "*after five years, and through the reform of their Statutes, the Autonomous Communities may successively extend their powers within the framework established in Article 149*."

[282] On this subject, see C. Chimenti, *Noi e gli altri,* vol. II, Part II, Giapichelli Editore, Turin; G. Amato, *Forme di Stato e Forme di governo (Forms of State and Forms of Government),* Il Mulino, Bologna, 2006; B. Caravita (ed.), *Le regioni in europa, esperienze costituzionali a confronto (Regions in Europe, a comparison of constitutional experiences),* Giampiero Casagrande Editore, Rome, 2002; G. De Vergottini, *Diritto Costituzionale Comparato (Comparative Constitutional Law),* Cedam, Padua; M. Iacometti, *Spain,* in *Comparative Constitutions,* Giapichelli Editore, Turin, 2005; F. Lanchester, *The Constitutions of Others,* Giuffrè Editore, Milan, 2005; R. Scarciglia – D. Del Ben, *Spain,* Il Mulino, Bologna, 2005.

also indicates that if such matters are not regulated within these Statutes, competence will be recognized as belonging to the State, whose prerogatives will prevail over those of the Autonomous Communities in the event of conflicts of competence for all matters not included in the list referred to in the previous Article 148 C.E.[283].

A systematic reading of the two provisions of Articles 148 and 149 of the Spanish Constitution therefore, makes it possible to affirm that both the former and the latter contribute to establishing a sort of insurmountable limit on the spheres of autonomy recognized respectively to the Communities and the State. On the one hand, the Autonomous Communities are recognized as having the possibility of going beyond the list of matters set out in Article 148, with the limitation of content being compliance with the subsequent Article 149 and the mandatory procedure being statutory reform. At the same time, on the other hand, despite the fact that the central State, in the silence of the territorial statutes, is recognized as competent in the remaining matters, the latter cannot include those provided for in the list in Article 148 of the Spanish Constitution.

The dual dimension of residuality gives rise to the broad consideration that the Spanish constitutional system recognizes the statutory autonomy of the individual Autonomous Communities, whose provisions are given constitutional importance.

A networked system of competences in which health matters are also recognized[284], which is included in both of the provisions under discussion.

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[283] Ex co 3 art. 149 C.E. "*Matters not expressly attributed to the State by this Constitution may correspond to the Autonomous Communities, by virtue of their respective Statutes. Competence over matters not assumed by the Statutes of Autonomy shall correspond to the State, whose rules shall prevail, in the event of conflict, over those of the Autonomous Communities in all matters not assigned to the exclusive competence of the latter. State law shall, in any case, be supplementary to the law of the Autonomous Communities*."

[284] It should be noted that, unlike the Italian system, in which even in Article 117 of the Constitution – relating to the division of powers between the State and the regions – the matter is referred to as "health protection", repeating the same wording as the previous provision in Article 32 of the Constitution, entitled "health protection". This correspondence does not exist in the Spanish Constitution. In fact, as analyzed in the previous paragraph, although there is no specific provision recognizing it as a right in its own right, the protection of the right to health – as a guiding principle of social and economic policies – pursuant to Article 43.2 of the Spanish Constitution is recognized as a duty of the "public authorities.". With regard to the division of powers defined in Articles 148 and 149 of the Spanish Constitution, it is worth noting here the exclusive use of the term 'health' as a matter of competence. This terminological difference allows us to better identify the conceptual

Just as the list of matters falling within the competence of the Autonomous Communities includes "health and hygiene"[285], the subsequent content of Article 149 provides for "foreign health. Fundamentals and general coordination of health, legislation on pharmaceutical products"[286] as a matter falling within the competence of the State.

Before analyzing the relationship between the two different areas of competence, it seems appropriate to focus on state competence in health matters. The latter is, in fact, composed of two different areas: external health, which is fully recognized as a matter of state competence, and part of internal health[287], which is divided between the state and local authorities.

Firstly, paragraph 16 of Article 149 of the Spanish Constitution identifies 'external healthcare' as an area of exclusive state intervention. This definition, which originated in the case law of the Constitutional Court (Tribunal Constitucional) ([288]), is now contained in Article 38 of the Organic Law of 1988, according to which it includes "activities carried out in relation to the supervision and control of possible health risks arising from the import, export, or transit of goods and international traffic" ([289]). This competence has lost its necessity, given the supranational relevance of the subject matter. As a result of this characteristic, the "transnational" issue also occupies an important place in Community legislation[290].

As regards internal health matters, it should be noted that these only partially fall within the competence of the state. At present, only certain aspects of this area

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and concrete difference between the substantive protection of the right and its organizational dimension.

[285] Art. 148, paragraph I, no. 21.

[286] Art. 149, paragraph I, no. 16.

[287] F.J. Sanz Larruga, *Las competencias del Estado, Comunitades Autonomas y Corporaciones locales en materia sanitaria,* in Goméz-Diàa Castroverde- Sanz Larruga (dir. Da), *Lecciones de Derecho Sanitario,* Universitade da Coruna, La Coruna, 1999.

[288] Of particular relevance is Judgment No. 329 of December 15, 1994, in which the Constitutional Court, in the context of the appeal for protection lodged against the Executive Royal Decree of the Organic Law of 1986

[289] Art. 38, paragraph II, ley organica General de Sanidad, followed by R.D. 1418/1986 of June 13, which specified its content, according to which external health has as its object the supervision, the prevention and elimination of health risks in the international traffic of persons, goods, animals, and plants passing through certain places in Spanish national territory (such as ports, airports, and border crossings).

[290] M. L. Alonso, *La proteccion constitucional de la salud,* op. cit.

are recognized, in particular: the foundations and general coordination of health care and legislation on pharmaceutical products.
Spanish healthcare legislation, which is part of a legal system characterized by strong regionalism, finds in the area of general coordination a response to the need to ensure integration between the different regional healthcare systems, preventing the creation of divergences and disparities that could potentially interfere with the functioning and stability of the entire system[291] . This competence is implemented through the establishment of the Inter-Territorial Health Council, initially provided for by the General Law of 1986, which, as will be highlighted in the following paragraph, has the specific task of ensuring the cohesion of the Spanish National Health System.

While the aspect relating to the general coordination of internal health care does not pose too many difficulties in terms of definition or implementation, the situation is different with regard to the 'bases de la sanidad' (health care bases) as a further area of state competence with difficult content boundaries.
The definition of this specific area of competence has been shaped by a wealth of case law from the Constitutional Court[292] , as a result of which it has been identified as the regulatory activity of the national legislature aimed at identifying a 'common regulatory denominator', the purposes of which can be summarized as follows: firstly, the identification of the 'bases'[293] makes it possible to limit the role of the state by ensuring the enhancement of the role of the autonomous communities[294] ; it also constitutes the limit from which their exercise becomes possible; and finally, this instrument makes it possible to ensure a minimum level of equality in the

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[291] Judgment No. 82 of 1983 Constitutional Court
[292] Judgment No. 32/1981 of July 28; Judgment No. 32/1983 of April 28; Judgment No. 69/1988 of April 19; Judgment No. 98/2004 of May 25; on this subject, see J. Tornos Mas, *La legislacion basica en la jurisprudencia del Tribunal Constitucional,* in *Revista Vasca de Administracion Publica,* 31, 1991.
[293] Basic legislation is explicitly recognized not only in the health sector, but also in the fields of education, environmental protection, and social welfare. according to the Constitutional Court, the 'basic' nature of certain matters derives from their interdependence throughout the national territory and their impact on the very foundations of the regulatory system (Judgment No. 32 of 1983 TC); on this point, see J. Jiménez Campo, *Que es lo basico? Legislacion compartida en el Estado autonomico,* in *Rivista Espanola de Derecho Constitucional,* 27, 1987.
[294] "*If it is the responsibility of the State to establish the foundations of healthcare, it is the responsibility of the Autonomous Communities, in accordance with the Constitution and their respective Statutes of Autonomy, to develop legislation and implement state regulations*," according to M. L. Alonso, *La proteccion constitucional de la salud,* cit.

application and enforcement of the right to healthcare throughout the national territory.

The system of regulatory references relating to the Spanish healthcare organization is completed by the so-called High Inspection competence.
This is a power that is not expressly referred to in the text of the Constitution, but derives from provisions contained in some Statutes of the Autonomous Communities. In particular, it was Article 18 of the Basque Statute that first recognized the State's power to verify the performance of the functions and powers attributed to it in the field of internal health.
Given the absence of a hierarchical relationship between the central government and the autonomous communities, it can be said that, in terms of content, high inspection does not translate into a generic supervisory power, but rather concerns a series of powers or activities intended solely to verify or ascertain that the autonomous community complies with state legislation[295]; from a formal point of view, this power can only be exercised by the State in relation to those Autonomous Communities whose Statutes expressly recognize it as a State power[296].

This power was then recognized in the Law on Cohesion and Quality of the National Health System in Article 76[297], in which, before listing the activities falling within this power—provided for in the second paragraph of the provision—the legislator took care to state that the exercise of this guarantee and verification function by the State would be carried out in compliance with the Constitution and the Statutes of Autonomy. The purely contingent nature of this matter, which makes its exercise subject to the explicit provision of within the Statutes, is reflected in the recent trend, found in the most recent Statutes, of its gradual elimination[298].

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[295] *"Understood in this way, high inspection constitutes a state supervisory power, not a generic and indeterminate control that implies legal dependence of the Autonomous Communities on the State Administration, but rather an instrument of verification or oversight that may, where appropriate, lead to the implementation of constitutionally established controls in relation to the Autonomous Communities, but not to replace them, turning said high inspection into a new and autonomous direct control mechanism*." Judgment No. 6/1982, February 22.
[296] E. Cobreros Mendazona, *Article 149.1.6,* in *Comentarios a la Constitución Española,* Wolters Kluer, 2008, p. 2377 ff. *"However, it should be reiterated that, in principle, all this will only apply in those autonomous communities in which the high inspection is expressly included in their* statutes."
[297] Chapter IX, Art. 76 Organic Law 16/2003, May 28.
[298] The Valencian Statute of 2006 does not provide for this type of competence being attributed to the central state.

With specific regard to internal health care, as mentioned above, the State is not recognized as having a predominant role in this context; on the contrary, this sector is shared at the central and territorial levels. In fact, aspects relating to internal healthcare are covered, at the constitutional level, both in the provision relating to the powers of the Autonomous Communities and in the subsequent provision relating to those of the State, although, in the latter case, with some clarifications.

Concerning internal health, there is therefore co-participation by various institutional actors, such as the central State, which is specifically assigned tasks of management and coordination – as well as supervision, where provided for at the territorial level – to which is added the definition of minimum and uniform regulations throughout the territory; This is accompanied by the role of the Autonomous Communities, which are recognized as having general competence in matters of 'health and hygiene', which, however, is subordinate, at least from a content point of view, to the regulations laid down at state level[299].

Therefore, although the Spanish legal system is classified as a regional state with well-defined boundaries, in which the Communities are granted a significant degree of autonomy, the situation is slightly different when it comes to the protection of the right to health. In this specific context, in fact, it appears that the central state assumes its traditional role as supreme regulator, given the importance that the protection of rights has in today's constitutional systems[300].

It is precisely this specific structure of the division of powers and, in particular, the role recognized to the central government in the protection of health,

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[299] According to part of Spanish doctrine, internal health is thus divided: through the matter of "health and hygiene" referred to in Article 148, which is attributed to the Autonomous Communities, collective health is protected; while the role of the State in "general coordination, basic legislation, and pharmaceutical legislation" referred to in the following Article 149 C.E. is responsible for the protection of individual health; thus, in particular M. L. Alonso, *La proteccion constitucional de la salud,* op. cit, p. 375 ff.

[300] L. Melica, *Il sistema sanitario spagnolo e la tutela della salute degli immigrati: spunti di riflessione (The* Spanish healthcare system and the protection of immigrants' health: food for thought*),* in *Rivista AIC,* 4, 2017; in describing the division of powers in healthcare matters in the Spanish legal system, he refers to "two territorial levels" to which the Constitution assigns public powers (pursuant to Article 43.1 EC), 'the central state and the autonomous communities: the former is assigned matters of objective national importance related to health, while the latter is assigned the organization and management of healthcare provision'.

that has made it possible to define by law a health care organization that, at first glance, does not seem too different from the model adopted in Italy.

3.3 Healthcare organization in Spain

Following this brief examination of the Spanish constitutional framework relating to health protection and the division of powers in the field of health, the establishment of the National Health Service is the implementation of Article 43 of the Constitution, which mandates public authorities to protect health as a guiding principle in legislative activity[301].
However, compared to the Italian case, where the constitutional provision of Article 32 of the Constitution was implemented through the enactment of the 1978 law, the Spanish healthcare system has acquired its fundamental features gradually, following a legislative development that can be divided into three key stages, often intertwined with the dynamics of decentralization typical of composite states.

The first important step in this evolutionary process was the General Health Law No. 14 of 1986, which established the Spanish National Health Service. This law had the important merit of establishing a system financed by general taxation[302], which was highly decentralized and tended to be universal and free of charge.

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[301] S. R. Vinceti, *La tutela della salute nelle democrazie stabilizzate (Health Protection in Stabilized Democracies),* Giappichelli, 2024, highlights how the wording of Article 43 of the Spanish Constitution, in particular the second paragraph, imposes an obligation on public authorities to organize and protect public health "but alongside the prescriptive aspects, it associates aspects of terminological vagueness that effectively reduce the implications of this provision by referring to specific laws for the detailed definition of the rights and duties deriving from it"; the very location of Article 43, according to the author, "has significant implications," as it is not possible to establish a sort of obligation for public authorities to set up health services or guarantee the free provision of care and, more generally, to define the various health services in detail, except for the indigent, to whom Article 15 recognizes the right to life and physical integrity; On this point, see also L. Cuocolo, *La tutela della salute tra neoregionalismo e federalismo. Profili di diritto interno e comparato (Health protection between neo-regionalism and federalism. Profiles of domestic and comparative law),* Giuffrè-Luiss University Press, 2005.

[302] This marks a departure from the previous model, which was based on a mutualistic system financed by social insurance and provided healthcare services to those who were productive, see A. Castellas, *Autonomia y solidariedad en el sistema de financiacion autonomica,* in *Papeles de Economia Espanola,* 83, 2000; J. M. Fernandez, *El nuevo sistema de financiacion autonomica,* in *Revista de Contabilidad y Tributacion,* Centro de Estudios Financieros, 228, 2000.

While the characteristics of universality and free access were to be implemented through subsequent regulatory measures, the 1986 law, in line with the principle of autonomy and the system of division of powers provided for in this area, designated a highly decentralized organizational model in which the entire healthcare structure was developed at different levels of government[303].

The overall healthcare organization system, as outlined by the 1986 law, follows a hierarchical structure headed by the Ministerio de Sanidad. The national organization is characterized by being composed of several autonomous healthcare systems structured on a regional basis, each of which is composed of different Areas de Salud (AS) whose division follows demographic and geographic indices.

Each Area, which is managed by the relevant Community, is in turn structured into two different levels of care: primary care, which is assigned to the Zonas basicas, and specialist care, which is provided by hospitals. The management of all the facilities within the different Areas, as well as all of these, is the responsibility of the respective Community, through the Plano Integrado de Salud (Integrated Health Plan)[304], which is a tool through which each Autonomous Community complies with the guidelines provided by the central level, ensuring coordination and equal care for all citizens.

Although the merits of this legislative intervention are widely recognized, the system structured in this way has given rise to numerous critical issues relating to the introduction of situations of inequality resulting from the uneven development of the healthcare systems of the autonomous communities, due in part to the absence of coordination mechanisms with the central government level[305] .

The existence of these critical issues led the legislator to intervene again on the matter with Law No. 16/2003 on the Cohesion and Quality of the SNS, which introduced mechanisms for coordination and cooperation between public

[303] This process had already begun in 1981 in Catalonia through Royal Decree 1517/1981 of July 8, followed by the creation of the Basque Health Service in 1993.

[304] Art. 54 General Health Law: "Each Autonomous Community shall draw up a Health Plan that shall include all the health measures necessary to meet the objectives of its Health Service. The health plan of each Autonomous Community, which shall comply with the general coordination criteria approved by the Government, shall encompass the set of plans of the different Health Areas."

[305] Thus A. Diurni, *Italy and Spain: a comparison of healthcare systems,* in *Law and Health,* 2017.

administrations in order to ensure the achievement of equality between the different territories.

This objective is clear from a first reading of the preamble to this law[306] and is achieved through the extension of the prerogatives reserved for the Inter-Territorial Council—a body for coordination between the center and the territories established by the previous Law of 1986—which finds its raison d'être in the exclusive state competence for the general coordination of health care.

Unlike in Italy, where decentralization took place gradually, in Spain, the 2003 law contributed to increasing the central role of the state at the expense of the broad margins of autonomy originally granted to the autonomous communities[307]. Therefore, even though it is a highly decentralized model of government, the enactment of the 2003 law, as well as its content, only confirms how the organizational dimension can be said to be recessive in the face of the protection of a fundamental right that requires not only healthcare services, but also that these be provided equally and uniformly throughout the national territory.

As regards the universality of the Spanish National Health System, this feature is the last to have been implemented in practice, through the General Public Health Law No. 33 of 2011. This legislative intervention, inspired by the principle of implementing a 'truly barrier-free' health policy[308], extended healthcare to all residents of the nation. It should also be noted that, following the legislative intervention of 2011, the guiding principle of Article 43 of the Spanish Constitution appears to have been effectively implemented, as, in addition to achieving the

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[306] "The experience gained in healthcare coordination since the approval of the General Health Law makes it necessary to seek a new model that builds on this experience and offers new tools that enable citizens to receive quality public healthcare services under conditions of effective equal access, regardless of their place of residence. The first contribution of the law to the new model is the definition of the areas in which collaboration between the state and the autonomous communities is necessary. In these areas, a common core of action is defined for the National Health System and the health services that comprise it. Without interfering with the diversity of organizational, management, and service delivery formulas characteristic of a decentralized state, the objective is that the assistance provided to citizens by public health services meets basic and common guarantees.

[307] On this point, see E. Griglio, *Unity and decentralization in the protection of the right to health in Spain,* in R. Balduzzi (ed.), *Constitutional systems, the right to health, and healthcare organization: Material points for comparative analysis,* Il Mulino, Bologna, 2009.

[308] Thus L. Melica, *The Spanish healthcare system and the protection of immigrants' health: food for thought,* op. cit.

principle of universality in protection, this law also had the merit of achieving a free healthcare system[309] .

4. Concluding remarks.

This brief analysis of the dynamics of the Spanish healthcare system allows us to draw broader conclusions on the issue of healthcare and its organizational structure. As has been emphasized several times in the previous pages, the right to health, in order to be protected, requires the establishment of an organizational structure aimed at providing healthcare services to citizens. As a social right to services, it is therefore addressed to the legislator, with a view to making this right effective.

These organizational structures are part of state systems characterized by a more or less marked decentralization of power, within which the protection of rights is caught in the difficult balance between uniformity of protection and territorial differentiation. To this end, the systems set up by two different systems have been analyzed: the Italian regional healthcare model and the Spanish system.

Given that the healthcare structure is characterized as the instrument through which the protection of the right to health of a nation's citizens is achieved, it has been demonstrated how the differences between the two regional models – clearly emerging from a theoretical-constitutional point of view – are diminished in the face of the need to protect the health of citizens.

In an attempt to summarize the reasoning, starting from the constitutional provision relating to what has been called the 'substantive dimension', it can be said that an analysis of both fundamental texts reveals an important underlying distinction: the right to health protection as a fundamental right of citizens, from which implicitly derives the necessary provision of organizational structures to ensure its effectiveness. In the Spanish Constitution, on the other hand, the right to health is never defined as a fundamental right, but rather as a guiding principle for public authorities, which become the privileged recipients of the constitutional provision

[309] Only a small part of the Spanish population is not covered by free healthcare, namely those with a particularly high ISEE index and freelancers, who are affiliated to the social security system of their respective professional association.

of Article 43 C.E., which less implicitly provides for a specific mandate for the legislator to implement health organization policies.

As regards the way in which relations between the center and the territories are structured in the field of health protection, here too the differences appear to be significant. Starting from the Italian text, Article 117 of the Constitution identifies health protection as a matter of concurrent competence involving the co-participation of the State and the regions; However, the requirements of unity and homogeneity in the protection of a fundamental right have specific constitutional significance, as they are ensured by the provision of the title of competence for determining essential levels of competence (Article 117(2)(m) CI), through which the State ensures a margin of intervention in all cases in which there is a need to ensure uniformity in the relevant legislation, specifically 'civil and social rights'.

With regard to the Spanish legal system, we can see that, taken as a whole, the system of division of powers between the State and the communities has its own peculiarities, deriving from the unique nature of the Spanish autonomous State[310] . This peculiarity is reflected in the health sector, which is divided into two macro aspects: foreign health, which is the exclusive competence of the state pursuant to Article 149 C. E.; and domestic health, which is divided between the competence of the state and the autonomous communities. In view of the general recognition of the latter's competence in matters of 'health and hygiene', the state legislator also has an important role to play in this specific sector, as it has the power to legislate in order to ensure the general coordination of healthcare, in terms of basic laws and pharmaceutical legislation.

By dividing the subject of internal health, the Spanish constitution has allowed the national legislature to intervene in all those cases where there is a need for consistency and uniformity in the protection of rights, arising from excessive differentiation between the health systems set up at the territorial level.

From an analysis of these two models, it can be said that, although both are distinguished by the diversity of the territorial model outlined in the constitution and, in particular, as we have seen, by the margin of autonomy reserved for local authorities, both systems are characterized by constitutional provisions—in the

[310] As briefly mentioned *in* paragraph 3

context of the division of powers—aimed at ensuring a prominent role for the central legislature. In the Italian case, the role of the State emerges as predominant over the role attributed to the regions through the title of competence of 'determining the essential levels of services concerning civil and social rights'; a deliberately broad formula with uncertain defining features, the use of which is often invoked to justify interventions that encroach on the sphere of regional competence, albeit justified by the need to protect the level of uniformity in the protection of rights necessary to ensure that the absolute principle of equality is not violated.

A similar expedient was used by the Spanish constitution, albeit in the specific context of healthcare, where state competence is provided for in the area of general coordination and basic legislation on the subject.

It therefore seems possible to affirm two essential facts: firstly, the organizational structure is a necessary element in ensuring the protection of health as a right of citizens; on the other hand, this structure must necessarily fit within the territorial structure of the nation in question, with the territorial area constituting its main point of reference due to its proximity to the community it serves.

However, this system does not allow the state decision-maker to play a secondary role; on the contrary, the latter plays a central role, acting as coordinator of the various subsystems and guarantor of the uniform protection of rights.

This central role is also confirmed in other contexts, such as the trend towards centralization that can be seen when analyzing the different strategies adopted by various legal systems in an attempt to stem the spread of Covid-19. This is a point that we will attempt to develop in the following pages.

CHAPTER IV

HEALTH PROTECTION DURING THE EMERGENCY

Summary: 1. Introductory considerations: *Salus Rei publicae suprema lex.* – 2. Regulatory management of emergencies in European Union law: what powers? 3. The Italian legal system: The (lack of) constitutional regulation of emergencies. – 3.1 Continued. Regulatory management of health emergencies in Italy. – 3.1.1 Continued. The (first) ruling of the Constitutional Court. – 3.1. 2 Continued. Loyal cooperation during the pandemic and the (second) ruling of the Constitutional Court. – 4. The management of Covid-19 in the federal state of Belgium. - 5. The state of health emergency: the French case – 6. Covid-19 pandemic, emergency or exception? The Spanish case. – 7. Concluding reflections

1. *Introductory considerations:* Salus rei publicae suprema lex

In developing the analysis, an attempt was made, first of all, to provide as complete a picture as possible of the evolution of the protection of the right to health, articulated in its dual role of substantive protection and organizational dimension; subsequently, an overview of the supranational dimension aimed at achieving its protection was provided, including an analysis of the growing role of the European Union and the World Health Organization, reflecting on the dual implications that this dimension has in the protection of the right (both in terms of substance and healthcare organization); The third chapter then analyzed how the territorial dimension, which is essential for the protection of rights, is often compromised whenever there is a need for homogeneity and uniformity in the protection of rights.

At this point in the analysis of the various aspects of the law covered by the research, it is useful to continue the reflection begun in the previous chapter on the flexibility of the intra-territorial organization of healthcare structures in the face of the role of the central state in an emergency context. This reflection necessarily starts from an analysis of the concrete context in which the health emergency caused by the Covid-19 pandemic was managed.

This crisis has overwhelmed the borders of individual nations and has very quickly taken on a supranational dimension and scope, hence the need for EU coordination in the emergency management of the pandemic, whose scale and severity required timely intervention by the institutions.

Returning to the analysis in the first chapter, it can be said that, although health protection has lost its connotations as an exclusive interest of the state[311] , it has been invoked as a justification for the use of emergency powers: *Salus rei publicae suprema lex*[312] . The analysis of the critical issues arising from the recent management of the pandemic, which is the subject of this chapter, is considered useful in order to obtain an in-depth reflection on how the protection of the right to health is structured, in particular, in the context of the relationships between the different levels of government responsible for its protection, studying their response and resilience capacities[313].

The Covid-19 affair has also reopened the perpetual constitutional debate on the necessity or legitimacy of constitutional provisions aimed at regulating exceptional and/or emergency situations, which, due to their intrinsic characteristics, require the centralization of certain powers in the hands of the executive.

Before analyzing how different legal systems have managed the current emergency in the name of health protection, it seems useful to make a brief theoretical digression on emergency governance and its possible need for constitutionalization.

The interventions required by this type of extraordinary situation take on the characteristics of what is commonly identified as 'emergency governance', which finds its justification in the state of exception[314], based on regulatory provisions

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[311] On the evolution of the right to health from a public interest to a fundamental right, see Chapter I;

[312] "Ollis salus populi suprema lex esto" (The health of the people is the supreme law) according to Cicero, *De legibus,* III, 3; T. Hobbes, *De Cive,* Chapter XIII.

[313] M. Gnes, *Pandemic emergency and resilience of the Italian system,* in M. Gnes (ed.), *Healthcare and public assistance put to the test by the pandemic. The Italian experience,* FrancoAngeli, 2023; in which the author uses the term resilience to describe the ability of a system (in this case, healthcare) to react to a crisis situation and return to the previous situation.

[314] C. Smith and Santi Romano address the issue of the state of emergency, identifying it as a factual element that can justify, at a regulatory and institutional level, constitutional distortions, namely "the strengthening of executive powers and the weakening of parliaments," according to O. Spataro, *Stato di emergenza e legalità costituzionale alla prova della pandemia (State of emergency and constitutional legality put to the test by the pandemic),* in *Federalismi,* no. 11/2022, p. 158ff.; for a

adopted rapidly in order to respond to temporary and exceptional needs that are abstractly suitable for derogating from constitutional rules, in the same way as a balance is struck between rights and values considered to be of equal importance.

The measures that fall within this context[315] are considered to must comply with two principles, namely: the principle of proportionality and the principle of cooperation. Accordingly, it is considered necessary that, first of all, the measures adopted to deal with the emergency are proportionate, i.e., involving a sacrifice no greater than that necessary to deal with the actual risk present[316]; to which is added the necessary involvement of all levels of government, giving priority to collaborative governance models[317] to ensure compliance with the principle of loyal cooperation.

In an era characterized by the proliferation of emergency situations[318] , the public debate on the need for derogations from the regulatory and political framework defined by the Constitutions in order to deal with such exceptional needs continues to remain central.

This difficulty is confirmed by the problematic nature of attempts to translate the so-called state of exception into regulatory terms[319] as an extra-legal element

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more detailed historical reconstruction of the 'state of emergency' and the consequences of its use, see C. Smith, *La dittatura,* 1921;

[315] Regulatory measures adopted for the protection of health in emergency situations can take the form of preventive or precautionary measures. The distinction between these derives from the different degree of risk to which they refer: while the principle of prevention is based on the management of concretely present 'risks', the principle of precaution refers to a subsequent moment, i.e., a phase in which these risks have materialized; These measures therefore relate to a phase in which the emergency subsides and all measures aimed at preventing the recurrence of critical situations come into play, putting in place precautionary mechanisms.

[316] D.U. Galetta, *The principle of proportionality between national law and European law (and with a look beyond the borders of the European Union),* in *Rivista italiana di diritto pubblico comunitario,* 2019 no. 6.

[317] The issue of the model of sub-state governance in regional states will be addressed in the next chapter.

[318] See G. Rolla, *Constitutional aspects of emergencies,* in *Rivista AIC,* no. 2/2015. According to the author, the abstract categorization of emergency situations has become impossible in recent times, given the apolitical nature of such events. These include extreme weather events such as floods and earthquakes, but also economic and financial crises that require institutional political intervention – such as the global economic crisis of 2008 and, more recently, the global health crisis caused by Covid-19, which will be discussed below.

[319] Starting from Schmitt's theory of the state of emergency as a danger to the very survival of an institutional legal system, which is therefore justified in overcoming the limits set by that system for the ultimate purpose of protecting its existence; in today's doctrine, emergency situations suitable for establishing the legal regime of the state of emergency are defined as *'sudden situations of difficulty and danger, tendentially transitory, which involve a crisis in the functioning of institutions operating within a given social structure',* according to G. Pizzorusso, *Emergenza stato di,* in

capable of justifying the activation of systems of power and regulatory sources other than those already established. This difficulty, as mentioned, is accompanied by the extreme recurrence of such exceptional events in recent years.

As a regulatory response to the proliferation of emergency circumstances, current constitutional charters share a tendency to incorporate provisions aimed at regulating, more or less specifically, emergency measures according to three common guidelines.

Firstly, there has been a veritable 'constitutionalization of the emergency', identifying, within the constitutional provisions, the specific cases in which the ordinary constitutional framework of the division of powers may be derogated from and the manner in which this should occur[320]. With the constitutionalization of the emergency, the extraordinary event—which legitimizes the derogation from the structures defined by the Constitution—becomes itself a constituted power, assuming the intrinsic character of constitutional legality.

In a position that can be defined as 'intermediate', it is possible to identify those Constitutions which, through specific provisions, establish the relations that must exist between constitutional bodies during variously named emergency situations, providing for mechanisms of control by elected assemblies over the executive or providing for qualified parliamentary majorities for the approval or renewal of the state of emergency[321].

Finally, there are constitutional documents that tend to subject the exercise of certain powers – necessitated by situations of extraordinary and exceptional importance – to substantial limits, such as, among the most recurrent, respect for the fundamental rights of the individual[322].

Enciclopedia Treccani, 1993; in which the transitory nature of such exceptional contexts becomes essential.

[320] G. De Minico, *Costituzionalizziamo l'emergenza? (Should we constitutionalize emergencies?),* in *Osservatorio sulle fonti,* 2020

[321] See on this point the constitutional law of Spain, § 5

[322] In the Federal Republic of Germany, the Basic Law of 1949 stipulates that it is not possible to suspend the right of association or strike, nor to violate the principle of dignity or infringe the essential content of a fundamental right; while the Spanish Constitution stipulates that the normal structure of constitutional powers must not be altered, see P. Cruz Villalon, *Estados excepcionales y suspensión de garantías,* Madrid, 1984. Finally, Article 27 of the American Convention on Human Rights prohibits the suspension of certain inalienable rights such as legal personality, the right to life, physical integrity, the prohibition of slavery, freedom of science and religion, political rights, nationality, and the judicial guarantees indispensable for their protection.

In light of this premise, individual legal systems have been identified that present these specific characteristics within their constitutional texts.

In the following pages, therefore, we will attempt to analyze the regulatory system on the basis of which the European institutions could effectively prepare a common line of action for all member states, in light of the principle of attribution on the basis of which the European Union itself exercises its functions in accordance with the prerogatives granted to it by the member states themselves and based on a situation of objective transnational relevance. In the first phase of the emergency, there was a fragmentation of regulatory responses from individual Member States, which established diametrically opposed containment and emergency management systems[323]; this was accompanied by a lack of guidance from the European institutions on how to prevent and manage the wave of infections, despite the transnational nature of the situation and the need for coordination between national measures, which, as we have seen[324], justify intervention by the European Union.

Below, we will proceed with a comparative analysis of the different ways in which some national states – such as Italy, Belgium, France, and Spain—have managed the health crisis, selected based on the presence of constitutional provisions aimed at identifying emergency clauses, in an attempt to verify whether the presence of

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[323] It is also useful to point out another fact emerging from empirical reality. Given the absence of uniform guidelines from the EU government apparatus, after an initial phase of divergence in the legislation adopted by individual states, these states subsequently adopted similar intervention strategies based on the regulatory management model adopted by Italy, the first member state to be most affected by the virus. This regulatory management model is characterized by a tendency towards centralization of governance limited to the executive branch, with two important consequences: the first is the increasing marginalization of the role of national parliaments in decision-making processes, which leads to the further marginalization of the territorial entities that make up the individual state entities. This emergency administration is therefore being replicated across several EU territories, despite the fact that it has led to significant critical issues in terms of compliance with the most basic constitutional principles concerning the division of powers between the state and the regions as outlined in national constitutions, as well as compliance with the institutional balance between individual bodies.
This constitutional discrepancy is felt differently depending on whether or not there are emergency clauses in the constitutions. On this point, see M. Gnes, *Emergenza pandemica e resilienza del sistema sanitario italiano* (Pandemic emergency and resilience of the Italian *healthcare system)*, op. cit.; I. Massa Pinto, *La tremendissima lezione del Covid-19 (anche) ai giuristi* (The tremendous lesson of Covid-19 (also) for lawyers), in *Questione giustizia*, 2020;

[324] In the first phase of the emergency, there was a fragmentation of regulatory responses by individual Member States, which set up diametrically opposed containment and emergency management systems; This was accompanied by a lack of guidance from the European institutions on how to prevent and manage the wave of infections, despite the transnational nature of the situation and the need for coordination between national measures, which, as we have seen, justify intervention by the European Union (see Chapter II, § 2 on this point).

these clauses has influenced the regulatory management of the Covid-19 emergency, ensuring compliance with the principle of legality, on the basis of which restrictions on fundamental rights are legitimized.
Compared to a regulatory system created from scratch by Italian institutions, there are indeed regulatory systems with emergency provisions of constitutional significance, particularly in France and Spain. The Belgian regulatory system occupies what could be described as an 'intermediate' position. Although it lacks constitutional provisions aimed at regulating the political and institutional balance in crises, it does contain clauses that allow for restrictions on fundamental rights without specifying any particular limits.

2. *Regulatory management of emergencies in EU law: what powers?*

In order to discuss the regulatory response provided by the European institutions during the COVID-19 pandemic, it is necessary to clarify the structure of the Union's competences[325] as outlined in its founding Treaties.
[326]These competences, as they correspond to a transfer of sovereignty from national states, are strictly defined in the founding Treaties (TEU and TFEU) and must be exercised based on specific guiding principles such as attribution and subsidiarity. In accordance with the first of these, the Union may only intervene in areas where it has been expressly conferred competence. With regard to the principle of subsidiarity, it is useful to note that this principle concerns the executive phase of the exercise of such powers, providing for the possibility of intervention by the Union only in cases where it is considered that the objectives of such action cannot be effectively achieved by the individual State.

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[325] The European Union acts in accordance with the principle of conferral, whereby the powers on the basis of which it may exercise its competences derive from a voluntary conferral – and consequent renunciation – of those powers by the Member States themselves. This voluntary surrender of sovereignty by the nations gives rise to three different types of powers: those that are exclusive to the Union, those that are shared with the Member States, and finally those that remain with the individual nations. on the development of the powers currently attributed to the European institutions, as well as the manner in which they are exercised, see R. Adam – A. Tizzano, *Manuale di diritto dell'Unione europea (Handbook of European Union Law),* Giappichelli, 2024.
[326] The principle of conferral is governed by Article 5(2) TEU, according to which *"The Union shall act only within the limits of the competences conferred upon it by the Member States in the Treaties to attain the objectives set out therein. Any competence not conferred upon the Union in the Treaties remains with the Member States."*

Following this necessary introduction, we will now proceed to analyze the European Union's regulatory framework for emergency situations in general and, in particular, for health emergencies.

As already noted[327], the field of health protection can be divided into two different areas of competence: although public health care is essentially a state competence, the Union acquires concurrent competence in cases where health protection and health care are threatened by emergencies which, due to their scale and characteristics, take on a cross-border dimension. In this particular context, the EU may intervene, albeit on a contingent basis, with a view, on the one hand, to ensuring a coordinated and consistent approach to the crisis by the Member States concerned and, on the other, in accordance with the principle of subsidiarity, the possibility for the EU to intervene with policies designed to complement those prepared by individual Member States in cases where the measures adopted by the latter prove ineffective in achieving the desired and hoped-for level of protection[328].

Proceeding in order, health protection falls within the exclusive competence of the Member States[329]. However, pursuant to Article 6 TFEU, the improvement of human health is included among the subsidiary competences in which the Union may intervene for the purpose of coordinating the various policies prepared by individual Member States.

Furthermore, as already mentioned, Article 168 TFEU(5) provides for the possibility of legislative action by the Parliament and the Council to establish 'incentive measures to protect and improve human health, in particular to combat major cross-border health scourges, measures concerning the monitoring, alert and combat serious cross-border threats to health." It should be noted that the Union may intervene through legislative acts to resolve common problems relating to blood and blood products, the veterinary and phytosanitary sectors, whose primary objective is the protection of public health, quality and safety of medicines and medical devices[330].

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[327] See Chapter II.
[328] Article 4 TFEU, paragraph 2, letter K
[329] Article 168 TFEU, paragraph 7.
[330] Article 168 TFEU, paragraph 4.

Therefore, attempting to summarize, there are two different spheres of competence in the health sector: one that is strictly state-based *in nature*, referring to the organizational dimension, which is necessarily national—thus referring to the organization of the National Health System as well as health crisis management plans—and one that is concurrent, in which the Union's intervention is contingent and subsidiary, taking the form of support for national regulations aimed at ensuring healthcare. In such contexts, EU intervention is envisaged for the sole purpose of improving the standards of protection established at the state level. A further possibility for EU intervention in the field of health protection, again falling within the sphere of concurrent competence, arises in the event of cross-border health crises[331].

Although healthcare is clearly a matter of competition in which EU intervention is possible but of little practical relevance, there are provisions worthy of attention in emergency situations. These provisions can in turn be divided into two different categories: the first includes all the acts intended to strengthen a system of information and management cooperation in emergency situations, while the second includes provisions aimed at establishing regulations to respond to crisis situations in individual Member States.

The latter objective is met by the Single Civil Protection Mechanism (ex Article 196 TFEU), which is accompanied by the subsidiarity clause (ex Article 222 TFEU).

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[331] In cases where the health risk is of a cross-border nature, the main responsibility remains with the national authorities, which are simply required to coordinate their respective policies and programs with each other, in agreement with the Commission. The same state reservation on this matter can be found in Article 35 of the Charter of Fundamental Rights of the EU, according to which everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws, confirming a purely national competence structure in which the Union's intervention takes on a possible coordinating role. Regarding the competences of the European Union in the field of health and emergencies, see, among others, P. De Pasquale, *The competences of the European Union in the field of public health and the Covid-19 pandemic,* in *DPCE online, No*. 2/2020, p. 2295 ff. F. Bestagno, *Health protection between the competences of the European Union and the Member States,* in *Studies on European Integration,* 2/2017, p. 317 ff.; P. Purnhagen, A. De Ruijter, M. L. Flear, T. K. Hervey, A. Herwing, *More competences than you knew? The Web of Health Competences for European Union Action in Response to the COVID-19 Outbreak,* in *European Journal of Risk Regulation,* Special Issue, 7/2020.

The Union Civil Protection Mechanism, established in 2001 and reformed by Decision 1313/2013/EU[332] and, following the pandemic, by EU Regulation 2021/836, aims to coordinate responses to natural or man-made disasters, "including the consequences of acts of terrorism, technological, radiological or environmental disasters, marine pollution, hydrogeological instability and serious health emergencies occurring inside and outside the Union"[333], in particular by supporting and complementing the prevention and preparedness efforts of Member States in response to such emergencies, strengthening cooperation and coordination between nations, and promoting solidarity between them, as "good disaster management saves lives, and effective coordination between the various entities involved is crucial to the successful implementation of the response to crises and disasters"[334].

Part of this mechanism, and worthy of mention, is RescUE, a European reserve of resources (human and material) to be mobilized in response to emergencies in Member States, through an Emergency Response and Coordination Centre (ERCC)[335]. The latter is responsible for monitoring natural disasters in Europe and responding to requests for assistance from Member States by coordinating the intervention of those who have offered to provide assistance through the provision of material, human, and technological resources.[336]

The set of instruments aimed at preventing and managing emergency situations at European level does not stop at the Civil Protection Mechanism, which is accompanied by the subsidiarity clause provided for in Article 222(1) TFEU[337].

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[332] Decision involving all 27 EU Member States as well as the United Kingdom, Iceland, North Macedonia, Montenegro, Serbia, and Turkey.

[333] EU Reg. 2021/836 Article 1, par. 1

[334] European Court of Auditors, *The Union Civil Protection Mechanism: coordination of responses to disasters outside the EU has generally been effective,* 2016 Report.

[335] See Guide to Europlanning, *Union Civil Protection Mechanism and RescEU,* www.guidaeuroprogettazione.eu

[336] E. Cirone, *Public Health and EU Law,* in *Observatory on Sources* 2/2021, p. 655.

[337] Although the subsidiarity clause is not only an important tool for managing natural and non-natural crises, but also and above all translates one of the key principles of the Union itself into a concrete institution, it has never been used in practice; this failure to use it is seen as a symptomatic sign of the political, rather than practical, significance of this provision, in this sense S. Villani, *The EU Civil Protection Mechanism: instrument of response in the event of disaster,* in *Rivista Universitaria Europea,* 2017, p. 141ff.

J. Jeller-Noller, *The Solidarity Clause of the Lisbon Treaty,* in *Think Global – Act European: The Contribution of 16 European Think Tanks to the Polish, Danish, and Cypriot Trio Presidency of the European Union,* 2011, p. 328 ff.

This provision, which can be invoked in the event of a disaster by an individual Member State in a crisis situation, commits the Union to mobilize all the instruments at its disposal to assist the requesting nation. In such a case, all Member States undertake to intervene jointly in a spirit of solidarity to provide their assistance under the coordination of the Council.

Council Decision 2014/45/EU implemented Article 222 TFEU by indicating the various means to be used in the event that a State requests the activation of the solidarity clause – the so-called integrated Union mechanisms for political response to crises IPCR – which also include the Civil Protection Mechanism[338] mentioned above, regulating its practical aspects. In order to activate this Mechanism, the Member State concerned must submit a request to the Presidency of the Council and the President of the European Commission through the Emergency Response Coordination Center.

As previously mentioned, mechanisms aimed at providing Community support to individual Member States that request it are complemented by centralized monitoring and surveillance systems designed to bring together useful information on health crises that are likely to become cross-border in nature.

To meet this specific objective, Decision 1082/2013/EU was adopted, introducing a system of cooperation on epidemiological surveillance and monitoring, as well as a system for planning and preparing a common response to complement individual national policies[339]. This decision therefore, aims to support and encourage cooperation and coordination between individual states in order to improve disease prevention and control within the Union. [340]

A surveillance network based on the obligation of national states to communicate data and information relating to the epidemiological control of communicable

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[338] Although the Civil Protection Mechanism, as a practical expression of the subsidiarity clause provided for in the Treaties (Article 222 TFEU), appears to be a valid tool enabling individual Member States to deal with disasters and emergencies which, due to their intrinsic characteristics, require human and technical resources that exceed the capabilities of a single nation, it is worth noting that none of the Member States requested its activation during the unprecedented emergency that overwhelmed the entire continent: Covid-19.

[339] Decision No. 1082/2013/EU of the European Parliament and of the Council of October 22, 2013, on serious cross-border threats to health, in OJ L 293, 1.

[340] F. Rolando, *Health protection in European Union law and the EU's response to the Covid-19 emergency,* in *The Covid-19 health emergency and European Union law. The crisis, the cure, the prospects,* *www.*Eurojus.it, special issue;

diseases and related special health issues, as well as information on the progression of epidemic situations[341], is complemented by the Rapid Alert and Response System through which Member States or the Commission itself report the development or emergence of a serious cross-border health threat[342]. On the basis of this information, the European Centre for Disease Prevention and Control[343], together with other relevant agencies, is responsible for developing a common strategy.

Finally, a Health Security Committee[344] manages the exchange of information between Member States and the Commission, coordinating with the latter the planning of Member States' preparedness and response to cross-border threats.

This regulatory framework includes the 's emergency management of Covid-19 by the Union follows the division of competences in the field of health between the latter and individual nations. As previously described, the health sector is characterized by being brought back into the realm of concurrent competences, where the Union's intervention—which is optional—is characterized by an approach aimed at integration and coordination with individual national policies. Therefore, even in the event of a cross-border health emergency, although the powers of the Union are increased, the full independence of individual nations in their approach to the emergency is reaffirmed, and the mechanisms put in place at the extra-state level are, once again, aimed at coordination rather than prevention.

Through this interpretation, it is therefore possible to analyze the individual actions taken by the Union during the pandemic emergency phase. This approach focused mainly on the so-called phase two as a phase of *de-escalation* of the spread of the virus. In this context, the EU's interventions can be divided into four specific lines of action[345]: firstly, measures were put in place to limit the spread of the virus;

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[341] Art. 6 Decision No. 1082/2013

[342] Art. 9 Decision No. 1082/2013

[343] Regulation 851/2004 of the European Parliament and of the Council of April 21, 2004, establishing a European Center for Disease Prevention and Control, in OJ L 142,1.

[344] Pursuant to Article 17 of Decision No. 1082/2013, this Committee shall be composed of representatives of the Member States and a representative of the Commission, who shall chair the body.

[345] These are lines of action established at the European Council videoconference on March 10, 2020, which was also attended by the President of the Commission, the President of the European Central Bank, the President of the Eurogroup, and the High Representative.

to ensure the supply of medical equipment; to promote vaccine research; and to prepare measures to contain the economic consequences of the crisis[346].

Initially, therefore, the European Union's interventions focused mainly on attempting to collect data and information in the context of the solidarity clause through the activation by the Presidency of the Council of the Union of the mechanism of the Union's integrated arrangements for political response to crises. With regard to the first priority, once the Commission had gathered information on the needs of the various Member States, it issued calls for tenders for the purchase of essential supplies at EU level. To this end, on the one hand, the Union Civil Protection Mechanism was activated, in particular the *RescEU* system, thanks to which medical teams were mobilized in countries where the healthcare system was under particular strain[347]. On the other hand, at the Community level, the suspension of European legislation on freedom of movement within the EU in order to curb the spread of infection, as well as the legislation prohibiting state aid, in order to encourage and facilitate the purchase of medical supplies essential for dealing with the emergency.

Although the Union has taken concrete action that has proved necessary and indispensable in attempting to respond to an unprecedented critical situation, some critical issues have arisen due to the total lack of coordination in the responses that each country prepared during the first phase of the emergency.

The need for a coordinated approach by all Member States appeared to be a fundamental objective of certain European actions, which, however, came during the downward phase of the pandemic; these actions were aimed at harmonizing the individual national responses across Europe with regard to the resumption of economic freedoms and the restoration of freedom of movement as guaranteed by the Treaties.

This objective was pursued in practice through the adoption of *soft law* instruments such as opinions and recommendations from the Parliament and the Commission.

[346] F. Rolando, *op cit.*

[347] In particular, two teams of healthcare personnel from Romania and Norway were sent to Milan and Bergamo, financed and coordinated by the Civil Protection Mechanism; Austria and Slovakia provided personal protective equipment (such as masks, suits, and ventilators) and welcomed Italian patients for treatment in their respective national facilities.

This context includes the European Parliament resolution of April 17, 2020, which urged Member States to develop common criteria for lifting isolation and other emergency measures, while also calling on the Commission to launch a shared exit strategy.

Also worthy of attention is the so-called European roadmap towards the lifting of coronavirus containment measures, which identifies common criteria for assessing the possibility of easing containment measures[348] and also sets out guiding principles for individual Member States for the common and coordinated management of the so-called phase two. These principles include the need for a coordinated approach in adopting such measures at the national level in order to ensure, on the one hand, that they are always supported by scientific evidence[349] and, on the other, that negative repercussions and political friction are avoided.

Particularly noteworthy is the emphasis that the Commission itself places on solidarity between Member States, defined as an essential element for the success of the second phase.

In view of the criticism levelled at the EU's (lack of) intervention during Covid, the reasons for this attitude on the part of the European institutions can be traced back to a division of competences which, even today, national strategies are still given priority, even in cases where it would be preferable to have a unified intervention strategy which, in the specific case of Covid-19, would have avoided an initial phase of confusion at national level, resulting in the introduction of inconsistent regulations.

However, it should be noted that the EU's intervention has been restored in areas related to its original economic purpose, such as measures aimed at suspending

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[348] Measures based on epidemiological criteria, on the assessment of the possible resilience of national health systems and adequate capacity to monitor epidemiological trends, see *Lifting Covid measures roadmap.*

[349] During the pandemic emergency, the need for legislative integration of technical and scientific knowledge provided by experts in the field was particularly felt; on this point, see A. Iannuzzi, Science-driven *laws and Covid-19. The relationship between politics and science in a state of health emergency,* in *Biolaw Journal,* 2020, no. 1; A. Patroni Griffi, *Scienza e diritto ai tempi dell'emergenza da Covid-19 (Science and law in the time of the Covid-19 emergency); C.* Acocella, *Ancora su diritto e tecnica. Le valutazioni tecnico-scientifiche come premessa delle decisioni politico-amministrative per affrontare l'emergenza pandemica da Covid-19 (More on law and technology. Technical and scientific assessments as a prerequisite for political and administrative decisions to deal with the Covid-19 pandemic emergency),* in *PA Persona e Amministrazione,* 2020.

provisions of the Schengen agreements, incentives for research, and the recovery of medical supplies.

3. *The Italian legal system: the (lack of) constitutional regulation of the state of emergency;*

A different example of regulatory management of the emergency can indeed be provided by the experiences of individual Member States, in particular Italy, as the first country to be affected by the potentially harmful virus.
It should be noted from the outset that, although the strategy adopted by the Italian institutions has been widely shared and replicated by other Member States, it has not been without criticism, mainly concerning the excessive centrality given to the Prime Minister in the adoption of measures, compliance with the principle of legality in the restriction of fundamental rights, and the lack of involvement of regional representatives in decision-making processes.

However, beyond the measures actually put in place by the Italian institutional apparatus—which can be summarized by the term *"lockdown"*[350] — Italy's management of the emergency follows the typical characteristics of situations that can be described as "exceptional government": characterized by centralization in favor of the executive branch at the expense of representative assemblies.
The peculiarity of the system set up by the Italian legal system to combat the threat of the virus does not lie so much in the governance measures used—such as the central role of the central decision-maker, to the detriment of loyal territorial cooperation, and of the executive, about the balance of powers of the state—but rather in the sources used for this purpose.
In order to understand the typical nature of the regulatory instruments provided by the Italian legal system to combat the pandemic emergency, it seems useful to

[350] On the 'regulatory chain' with which Italian institutions, in particular the Council of Ministers, attempted to manage the pandemic emergency period, see §. 4

provide a brief overview of the rules that the Italian Constitution does (not) reserve for emergency situations.

The constitutionalization of emergencies takes on particular significance in the Italian case, given the absence of any express provision aimed at regulating the possible institutional response to emergency situations. with particular reference, on the one hand, to the balance between the centers of institutional power and, therefore, in concrete terms, to the relationship between the executive and legislative branches, and, on the other hand, to the systematization of parallel regulatory sources specifically aimed at regulating and responding to emergency situations[351].

Although the absence of emergency clauses in constitutional texts may be due to empirical and factual difficulties, such as the ontological obstacle of systematizing—and therefore positivizing—the factual situations that could lead to the activation of such extraordinary management, in the Italian case these are accompanied by specific historical reasons. The preparatory work of the Constituent Assembly shows how much this debate was influenced by the heavy legacy of the historical precedent set by Article 48 of the Weimar Constitution, which was used as a regulatory expedient to paralyze and subvert the German constitutional order during the Nazi dictatorship[352] . To this end, the constituent assembly chose to avoid providing for a 'state of emergency' as a justification for resorting to exceptional law, as the latter is a linguistic term with an excessively vague meaning and, as such, susceptible to potentially broad and dangerously subversive interpretations[353].

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[351] The structure of institutional balances and the systematization of regulatory sources during emergency periods are, in fact, the main critical issues around which the doctrinal debate on the constitutionalization of emergencies revolves; on this point, see S. Romano, *The Modern State and its Crisis. Essays on Constitutional Law,* Milan, Giuffrè, 1962.

[352] This provision authorized the Reich President, in the event of grave danger, to take the necessary measures to restore security and public order, including the use of force and the suspension of fundamental rights; see G. Bognetti, *Europa in crisi: due studi su alcuni aspetti della fine della II Repubblica francese e la Repubblica di Weimar (Europe in crisis: two studies on some aspects of the end of the Second French Republic and the Weimar Republic*), Milan, 1991.

[353] Specifically, there were two conflicting positions during the Assembly's work. On the one hand, Hon. La Rocca requested the inclusion of a provision on the so-called state of siege, which could be declared only by the Head of State in light of verifiable situations of 'emergency and the need for extraordinary measures to guarantee the life of the country'; this proposal was rejected precisely because of the need it evoked to provide for scenarios in which dictatorial powers could be activated,

Despite the absence of express provisions, emergency regulations find their way into the Italian Constitution, as they can be found "in principle"[354] through the interpretation of the provisions governing the state of war and emergency decrees, Articles 78 and 77 of the Constitution, respectively.

From the provision of Article 78 of the Constitution, it is possible to derive, on the one hand, the basis for the structure of powers defined in emergency situations, establishing that the "state of war is decided by the Chambers." In fact, the constitutional text affirms the centrality of the representative Assembly even in extraordinary situations, reserving to the Head of State the power to "declare" a state of war[355].

On the other hand, Article 77 of the Constitution is the provision from which guidance can be drawn regarding the allocation of legislative power in emergencies. The provision in question regulates the institution of emergency decrees as a primary legislative instrument within the competence of the government, which is exceptionally vested with legislative power in cases where situations of particular extraordinary urgency must be addressed[356].

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which were 'contradictory to the very logic of the Constitution', so the Commission of 75 decided to present a constitutional draft without an emergency clause.

It was therefore considered that the risk arising from the possible positivisation of hypotheses of derogation and/or suspension of fundamental rights and freedoms was greater than that arising from a lack of emergency regulations; Constitutional Commission, II Subcommittee, *Report by Hon. Deputy La Rocca, On Executive Power,* http://legislature.camera.it/_dati/costituente/lavori/relaz_proposte/II_Sottocommissione/34nc.pdf; Constituent Assembly, Constitutional Commission, Second Subcommittee, *General Appendices – Topics or articles not included in the Constitution – Suspension of constitutional rights and declaration of a state of siege,* Saturday, January 11, 1947. However, the debate did not end there, but resumed following the presentation of the Crispo amendment, according to which *"the exercise of rights of freedom may be limited or suspended for reasons of defense, determined by time or by a state of war, as well as for reasons of public order, during a state of siege";* thus, only a state of siege was identified as a legitimate reason for the government to exercise the necessary extraordinary powers. However, the amendment was rejected on the grounds that the very provision for the suspension of rights was equivalent to a suspension of democracy, which was incompatible with the physiology of the new constitutional text.

[354] M. Simoncini, G. Martinico, *From emergency to risk in comparative public law: an introduction,* in *DPCEonline,* 2022, p. 73

[355] The power that in the monarchical tradition was reserved for the Head of State is thus divided into two moments, namely the deliberative and the declarative: that is, the power to declare and deliberate on a state of war, thus emphasizing the preeminent role of the body representing the will of the people, not only in ordinary times, but also in exceptional circumstances. See B. Cerchi, *State of siege and suspension of freedoms in the work of the Constituent Assembly,* in *Quarterly Review of Public Law,* 1981, p. 1121 ff.

[356] The factual requirement for the government to issue decree-laws corresponds to the presence of 'extraordinary cases of necessity and urgency'. The excessive vagueness of the terminology used has given rise to a doctrinal debate about the meaning to be attributed to it. Different positions have

In such contexts, in order to meet the typical need for a rapid regulatory response, the Constitution provides for the possibility of intervention by the executive in a shorter time frame than the ordinary legislative process. However, to balance this prerogative, the legislation remains in force for a limited period of 60 days, after which it loses its effectiveness if it is not transposed into ordinary law[357] by Parliament.

Therefore, although the Italian Constitution may represent an example of a failure to take a position on the nature and powers deriving from a hypothetical state of emergency, these can be inferred through an interpretation of the provisions governing the state of siege and emergency decrees. These provisions, first and foremost, emphasize the absolute centrality of the Parliamentary Assembly even in exceptional situations—relevant both in the deliberation of a state of war pursuant to Article 78 of the Constitution and in the procedure for converting decree-laws pursuant to Article 77 of the Constitution—whose intervention is ensured by virtue of the popular sovereignty it expresses[358].

Therefore, although emergency regulations may be interpreted through certain provisions of the Constitution, the latter, mainly for historical reasons, does not contain any rules expressly regulating emergency situations; such regulations can rather be found in sources of primary sub-constitutional law.

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emerged on this point. On the one hand, the qualification of "necessity and urgency" as a hendiadys or as two distinct requirements with independent terminological value; on the other hand, the subjective or objective meaning to be attributed to it. According to the subjective thesis, 'The government, assuming political responsibility, decides autonomously what is to be considered necessary and urgent in relation to its political agenda' (R. Bin - G. Pitruzzella, *Le fonti del diritto,* Turin, 2023); This is contrasted by the objective thesis, which equates the existence of situations of extraordinary necessity and urgency exclusively with cases in which there is 'a material and absolute impossibility of applying (...) the rules governing the life of the State and the need not to apply the existing ones, but to enact new ones'. In other words, according to this approach, an extraordinary case should 'be equivalent to an unusual or abnormal situation, which needs to be addressed as an objective or real necessity, in which there is an urgent need to intervene with appropriate measures, on the assumption that there are no legal means available in the legal system for this purpose' (A. Morrone, A. Morrone, *Fonti normative. Concetti generali, problemi, casi,* Il Mulino, Bologna, 2022; on this point, see also C. Esposito, *Decreto-legge,* in *Enciclopedia del Diritto,* IX, Milan, Giuffrè, 1962).

[357] Through the conversion law, in fact, it is envisaged that Parliament will reclaim the legislative function exceptionally exercised by the executive, see V. Crisafulli, *Lezioni di diritto costituzionale,* 1961, Cedam; A. Celotto – E. Di Benedetto, *Art. 77,* in R. Bifulco – A. Celotto – M. Olivetti (eds.), *Commentario alla Costituzione,* vol. II, Utet, Turin, 2006;

[358] G. Rivosecchi, The *regulatory powers of the Government in times of emergency: when the exception becomes the rule,* in *Constitutional Law,* 1, 2024;

The main source of emergency legislation is contained in Legislative Decree No. 1 of 2018 – the Civil Protection Code – which provides for the possibility of declaring a state of national emergency on the basis of the verification of all the factual requirements[359].

The declaration of a state of emergency of national importance directly gives the Head of the Civil Protection Department the power to intervene to meet the needs and emergencies arising from such situations[360], through a specific regulatory instrument: *extraordinary* orders, which may derogate from the legislation in force within the insurmountable limits of compliance with the principles of the legal system and European legislation[361].

The provisions of the Civil Protection Code do not exhaust the legislative framework established for the regulatory management of emergency situations; specific references to health emergencies are contained in the law establishing the National Health Service. Article 32 of Law No. 833 of 1978 provides for the possibility for the Minister of Health to adopt contingent and urgent orders on matters of hygiene and public health safety, accompanied by the same power for regional presidents and mayors to address the same needs within the more limited territorial scope of their jurisdiction[362].

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[359] Pursuant to Art. 7 of Legislative Decree 1/2018, "a) emergencies related to natural disasters or those resulting from human activity that can be addressed through measures that can be implemented by the individual bodies and administrations normally responsible;

b) emergencies related to natural disasters or those resulting from human activity which, due to their nature or extent, require the coordinated intervention of several bodies or administrations and must be addressed with extraordinary means and powers to be used during limited and predefined periods of time, regulated by the Regions and the Autonomous Provinces of Trento and Bolzano in the exercise of their respective legislative powers;

c) emergencies of national importance related to natural disasters or man-made events which, due to their intensity or extent, must be addressed immediately with extraordinary means and powers to be used during limited and predefined periods of time in accordance with Article 24;

[360] "Although it has no specific competence in health matters, the Department of Civil Protection is institutionally responsible for emergency management in Italy and is best equipped to carry out organizational tasks and/or tasks with financial implications (...) as well as instrumental tasks)," according to M. Gnes, *La resilienza del sistema sanitario italiano e l'emergenza Covid-19 (The resilience of the Italian healthcare system and the Covid-19 emergency),* op. cit.; on this subject, see also L. Durst, *Fragility and fragmentation of the right to health in times of pandemic,* in C. Caporale, C. Collicelli, L. Durst (eds.), *After the pandemic. Notes for a new healthcare system,* in *Research ethics, bioethics, biolaw, and biopolitics,* II, 2022;

[361] Article 25 of Legislative Decree No. 1/2018; Official Gazette January 22, 2018

[362] Article 32 of Law No. 833/1978, Official Gazette of December 28, 1978; Articles 50-54 of Legislative Decree No. 267 of August 18, 2000.

Therefore, although the Italian regulatory system was not lacking in instruments that were theoretically suitable for dealing with a health crisis, the recent pandemic has shown that this regulatory framework was not adequate to deal with an emergency situation such as the one that actually occurred.

3.1 Continued. Regulatory management of the health emergency in Italy

Based on the above, it can be said that, although lacking a specific constitutional framework, the Italian legal system had numerous alternatives for managing, at the regulatory level, the needs associated with the Covid-19 pandemic emergency. However, as will be discussed in more detail in the following pages, the management methods introduced refer to regulatory instruments that are parallel to those already provided for in the regulatory provisions prior to the emergence of the emergency.

Proceeding in order, it should be noted that the first act that initiated the regulatory management of the emergency was the declaration of a state of emergency of national significance[363] – issued on January 30, 2020 – and the first orders issued by the Head of the Civil Protection Department, as provided for by the legislation already in force.

In view of this, the government subsequently launched what has been repeatedly referred to as a 'parallel model' of emergency management, through the issuance of a first decree-law, No. 6 of 2020. This legislative act provided for the possibility, on the part of the Prime Minister, to introduce possible measures to deal with the ongoing emergency situation.

This measure was heavily criticized, mainly for two fundamental reasons that highlighted the discrepancy between the text in question and a number of provisions

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[363] Declaration of a state of emergency as a result of the health risk associated with the onset of diseases caused by transmissible viral agents, pursuant to Article 7(1)(c) of Legislative Decree No. 1 of January 2, 2018, Civil Protection Code. On the powers granted to the Head of the Civil Protection Department, see G. Azzariti, *L'eccezione e il sovrano. Quando l'emergenza diventa ordinaria amministrazione (The exception and the sovereign. When emergency becomes routine),* in *Costituzionalismo.it,* February 2010; C. Pinelli, *Un sistema parallelo. Decreti legge – ordinanze d'urgenza nell'esperienza italiana (A parallel system. Decree laws – emergency orders in the Italian experience),* in *Dir. Pubbl., 2*, 2009.

of constitutional significance. Firstly, there were strong objections to the provision granting blank delegation of powers[364] to the Prime Minister, whose ability to introduce 'further measures' – not otherwise specified – was not counterbalanced by any procedural process[365] required for the adoption of such measures.

The individual decrees issued unilaterally by the Prime Minister following this primary legislative intervention were accused by many of being contrary to the Constitution due to the breadth of the delegation of powers granted to the Prime Minister, which did not allow for full compliance with the principle of legality, understood in both a formal and substantive sense, which underpins the regulatory system outlined in our Constitution[366]. This necessity becomes even more pressing, as in the case discussed at, when it concerns instruments that introduce severe restrictions on the exercise of certain constitutionally protected rights[367].

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[364] Article 2 of Decree Law No. 6/2020 provided for the possibility for the Prime Minister to introduce "additional measures to contain and manage the emergency."

[365] The decree merely provided for the possibility that individual Prime Ministerial Decrees could be adopted on the proposal of the Minister of Health, in agreement with the Ministers of the Interior, Defense, Economy, and Finance, and any other competent ministers.

[366] The criticism levelled at the system of restrictions introduced by the decrees mainly concerned the focus of their intervention. In fact, in an attempt to slow down the spread of the virus, one of the measures introduced was a general ban on leaving one's place of residence, which inevitably led to an unprecedented restriction of numerous fundamental rights , including personal freedom, freedom of movement, and freedom of assembly, but also the freedom to profess one's faith, insofar as people were not allowed to leave their homes even for this purpose (see L. Cuocolo, *Constitutional rights in the face of the Covid-19 emergency: the Italian response,* in *Constitutional rights in the face of the health emergency. A comparative perspective, Federalismi.it,* Covid Emergency Observatory).

[367] M. Gnes, *The resilience of the Italian healthcare system and the Covid-19 emergency,* op. cit. refers to 'a new emergency law based on a strategy of containing the spread of the virus, essentially through the adoption of measures aimed at imposing social distancing, limiting the freedom of movement of persons (but also affecting other constitutionally guaranteed rights and freedoms) to be adopted by Prime Ministerial Decree'; in particular A. Algostino, *Covid-19: primo tracciato per una riflessione nel nome della Costituzione (Covid-19: first outline for reflection in the name of the Constitution),* in *Rivista AIC, 3*, 2020; traces the rights limited to the constitutional provisions relating to: freedom of movement (Article 16 of the Constitution), freedom of assembly (Article 17 of the Constitution), freedom of religion (Article 19 of the Constitution), the right to strike (Art. 40 of the Constitution), the right and duty to work (Art. 4 of the Constitution), private economic initiative (Art. 41 of the Constitution), the right to education (Arts. 33 and 34 of the Constitution), and freedom and secrecy of correspondence (Art. 15 of the Constitution). Although some had also invoked the possibility of attributing these measures as limiting the right under Article 13 of the Constitution – the right to the inviolability of personal freedom – which subordinates any limitations to the reserve of law and the reserve of jurisdiction, administrative case law has repeatedly affirmed the legitimacy of the measures introduced. This position was then confirmed by Constitutional Court ruling no. 127/2022, which did not recognize the limitation referred to in Article 13 of the Constitution, as "the latter refers to restrictions mediated by the use of physical force, as well as those that involve the subjection of the person to the power of others"; on the ruling, see V. Zagrebelsky, *Covid quarantine in the case law of the Constitutional Court and the European Court of Human Rights,* in *Dir. Pen e proc.,* 2022.

The restrictions introduced to deal with the pandemic were justified by the need to protect public health, but some criticism has been raised both on the substantive front and with regard to formal aspects of the measures introduced.
Firstly, many have argued that, although justified by the need to protect the right to health—as a collective interest—this right, although textually qualified as "fundamental"[368], cannot be considered to have a higher value than other rights of equal constitutional importance[369]. On the other hand, with regard to critical issues relating to the formal aspect, despite the current emergency situation, it has often been argued that the exceptional measures introduced lacked the characteristics necessary to ensure that the current democratic constitutional system was not violated[370] .

To address these critical issues, the government decided to intervene with a second decree-law - Decree-Law 19 of 2020 - whose main measures can be traced back to two main lines of action. Firstly, this regulatory intervention made it possible to strictly indicate within the primary source the individual measures limiting fundamental constitutional rights that could potentially be introduced, again through the instrument of the Dpcm, in order to deal with the emergency, so as to bring the system of sources used back within the principle of legality.
Secondly, Decree Law No. 19 deals with proceduralizing the process through which such measures could be introduced, attempting to recognize Parliament's role in emergency management that could go beyond the mere conversion of individual measures adopted by the Government. Under the new rules, individual DPCM decrees could be adopted on the proposal of the Minister of Health, subject to the mandatory opinion of the Minister of Defense, the Minister of Economy and

[368]On the provisions of Article 32 of the Constitution under Chapter I, § 3;
[369] Constitutional Court ruling no. 85/2013 "one cannot agree with the assumption (...) that the adjective 'fundamental' contained in Article 32 reveals the preeminent nature of the right to health over all other rights of the individual. Nor does this Court's definition of the environment and health as 'primary values' (ruling no. 363 of 1993((…)) imply a rigid hierarchy among fundamental rights. The Italian Constitution, like other contemporary democratic and pluralistic constitutions, requires a continuous and mutual balance between fundamental principles and rights, without any of them claiming to be absolute."
[370] To this end, it is required that 'in order for exceptional measures to remain within the framework of the Constitution and a democratic form of government, (...) certain requirements must be met', such as: the temporary nature of the measures introduced, proportionality 'with respect to the aim pursued', and respect for institutional forms and balances ; thus A. Algostino, *Covid-19: first outline for reflection in the name of the Constitution,* op. cit.

Finance, and other relevant ministers. This was accompanied by the obligation on the Prime Minister to report the individual measures to both Houses within one day of their publication and, in any case, there was an obligation to report to the Houses on the emergency measures adopted every two weeks[371] .

Despite the attempt to remedy the constitutional inconsistencies of the emergency system as outlined in the previous Decree Law No. 6, numerous questions were raised regarding the constitutional legitimacy of the regulatory framework for emergency management based on the one-to-one relationship between decree laws and Prime Ministerial Decrees, even after the introduction of Decree No. 19/2020.

3.1.1 Continued. The (first) ruling of the Constitutional Court

The Court responded to these questions with ruling no. 198 of 2021[372] following a question of constitutional legitimacy that affected provisions contained in both Decree No. 6 and the subsequent no. 19.

The question[373], raised by the Justice of the Peace of Frosinone, concerned Articles 1, 2, and 3 of Decree Law No. 6/2020 and Articles 1, 2, and 4 of Decree

[371] For a complete examination of the regulations introduced by Decree Law No. 19 of March 25, 2020, see F. Cintioli, *On the* lockdown *regime in Italy. Notes on Decree Law No. 19 of March 25, 2020,* in *Federalismi.it, Covid Emergency Observatory,* 2020.
[372] For an analysis of the ruling, see M. Francaviglia, *The system of Prime Ministerial Decrees under scrutiny by the Constitutional Court. First impressions of Constitutional Court ruling no. 198/2021,* in *Diritti Comparati,* 2022; A. Lamberti, The *Constitutional Court and the forced rescue of the DPCMs: observations on the margins of Constitutional Court, judgment no. 198/2021, in Supreme Courts and Health,* 1/2022; M. Cavino, *The nature of the Prime Ministerial Decrees adopted in the first phase of the COVID emergency. Reading of Constitutional Court no. 198/2021,* in *Federalismi.it,* no. 25/2021;
[373] the case in *question* arose following the imposition of an administrative penalty for violation of the prohibition on leaving one's home provided for in the Prime Ministerial Decree of March 22, 2020; the referring court decided to raise the question of constitutionality given the alteration to the system of sources not justified by the regulatory framework provided for by the Constitution regarding the regulatory framework for extraordinary situations provided for in favor of the Government by Articles 76 and 77 of the Constitution; from which did not derive the possibility of introducing administrative penalties through secondary instruments. The Attorney General's Office, representing the Prime Minister, objected to the admissibility of the question raised on two grounds. Firstly, the lack of relevance with regard to the provisions contained in Decree Law 6/2020, which were challenged as unlawful, given that they had been repealed by the subsequent Decree Law 19/2020; secondly, the deemed irrelevance of the parameters invoked – such as Articles 76 and 77 of the Constitution – concerning the circumvention of the division of powers at institutional level,

Law No. 19/2020 in relation to the same parameters referred to in Articles 77 and 78 of the Constitution, insofar as these provisions altered the regulatory system of sources on the one hand, which led, on the other, to an imbalance in the separation of powers in favor of the Government, which was not otherwise legitimized except in the event of a "declaration of a state of war"[374] from which the Constitution derives the possibility for the latter to exercise the necessary powers, which did not actually occur during the health emergency.

The Court's ruling—although it came after the regulatory *chaos* of the first phase of the emergency—has the merit of bringing order to the definition of the different sources that were intertwined in an attempt to regulate an unprecedented emergency situation.

In a ruling rejecting the case, based on the primary classification of the various measures that could be introduced by the Government on the one hand, and, on the other, the simultaneous 'parliamentarization'[375] in the procedure for their adoption – which always took place under Decree Law No. 19 – the Court divided the acts adopted during the emergency into two categories: necessary administrative acts and necessary ordinances. Although these acts share the extra-legal premise of the emergency situation that determines the need for their adoption, they are distinguished by being exclusively Dpcm based on primary legislative acts that establish their content, while necessary ordinances, as *extra ordinem* acts*,* are capable of taking on various contents in order to adapt flexibly to changing situations[376].

It seems important to highlight the discrepancy in the argument used by the Court, which uses the parliamentary process in the adoption of DPCMs as the basis for its decision to reject the appeal. However, although this procedural expedient is worthy of ensuring democracy in decision-making at such a delicate time, it is

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given that the complaints raised concerned rather the respect of the principle of legality – understood in a substantive sense – from the point of view of the absence of a legal reserve concerning acts introducing measures limiting fundamental rights.
The first of the two exceptions raised by the Attorney General's Office was upheld by the Court, which, in its judgment, based its decision on the question of legitimacy concerning exclusively the provisions of Decree Law 19/2020.

[374] Governed by Article 78 of the Constitution, referred to as the constitutional parameter against which to assess the question of legitimacy raised;

[375] Thus M. Rubechi, *op. cit.;*

[376] Constitutional Court ruling no. 4 of 1977;

difficult to reconcile with the legal category to which the DPCMs themselves belong. [377]As necessary administrative acts, they do not require the participation of the Chambers in their adoption, as they are an expression of the discretionary power of the Administration, which must choose which of the various measures prepared in the legislative arena is most suitable to meet the needs of the specific case.[378] .

3.2 Continued. Loyal cooperation during the pandemic and the (second) ruling of the Constitutional Court.

Another critical element in the regulatory management of the health emergency by the Italian government concerns the almost total absence of regional bodies in this management activity, with the consequent circumvention of the principle of loyal cooperation as a cornerstone of the Italian regional state following the 2001 Constitutional Reform of Title V[379].

The critical implications of the absolute centralization of pandemic management in favor of the executive branch have not been limited to the distortion of the system of sources and balances of power, but have also been reflected in the division of powers between the central government and the regions, as well as in the principle of loyal cooperation.

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[377] See M.S. Giannini, *Potere di ordinanza e atti necessitati (Powers of order and necessary acts),* in *Giur. compl. cass. Civ.,* XXVII, 1948; R. Cavallo Perin, *Potere di ordinanza e principio di legalità. Le ordinanze amministrative di necessità e urgenza (Powers of order and the principle of legality. Administrative orders of necessity and urgency),* Giuffrè Milano, 1990;

[378] see M. Bignami, *Chiacchiericcio sulle libertà costituzionali al tempo del coronavirus (Chatter about constitutional freedoms in the time of coronavirus),* in *Questione Giustizia,* 2020;

[379] The constitutional reform brought about by Constitutional Law 3 of 2001, already anticipated by the previous Constitutional Law 1 of 1999 (full statutory autonomy for the regions), constitutes the greatest constitutional reform implemented to date, approved by a large majority in Parliament, although it was not sufficient to rule out the possibility of a subsequent constitutional referendum, which confirmed the outcome. This reform changed the Italian state structure from a centralized state to a federal one, increasing the statutory autonomy of ordinary regions and reforming the system of division of powers provided for in Article 117 of the Constitution. This reform did not complete all the possibilities for federal implementation provided for by the Italian Constitution, which in the third paragraph of Article 116 provides for the possibility for regions to acquire 'further forms of autonomy', which will be discussed in the following chapter, cf. Astrid, *La riforma del Titolo V della Costituzione e i problemi della sua attuazione (The reform of Title V of the Constitution and the problems of its implementation),* 2002;

Although, as analyzed above, Decree Law No. 19 had the merit of bringing the system for adopting the measures introduced from time to time to deal with the emergency back into line with the Constitution, providing for mechanisms for the inclusion of Parliament in this process, no corrective measures were provided for with regard to the involvement of the regions in this forum.

Article 3 of Decree Law No. 6/2020 provided for the possibility of consulting the presidents of the individual regions or the president of the State-Regions Conference in the process of adopting the Dpcm, depending on whether the measures to be introduced concerned a single regional territory or several regions. This was a very limited scope for intervention, given that the pandemic, due to its naturally unpredictable spread, had a different impact on different regional territories. For this reason, agreement with the respective regional presidents seemed a desirable solution, at the very least, in order to bring different needs to the attention of the central government.

A greater scope for regional intervention was provided for in the decrees only in cases of situations of increased health risk occurring in their territory[380]; intervention that was expressed in the exclusive possibility of introducing further restrictive measures, within the scope of their powers and without affecting productive activities and those of strategic importance for the national economy (Article 3 of Decree Law 19/2020).

However, the scope for regional intervention was not limited to the – limited – provisions set out in the executive's decree-laws, as the Civil Protection Code (Legislative Decree 1/2018) requires agreement with the presidents of the regions concerned in the process of adopting *extraordinary* orders by the Head of the Civil Protection Department. Added to this framework is the possibility for mayors – governed by both the decrees and Article 32 of Law No. 833/1978 – to issue contingent and urgent orders within their territory.

Although emergency regulatory management – also as a result of the rules introduced by the aforementioned decrees – is highly hierarchical in favor of the central government, precluding significant margins for regional intervention,

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[380] G. Delledonne, C. Padula, *Centralization and differentiation in the management of the pandemic emergency,* in *Le Regioni,* 4/2020;

practical experience has shown us that, while remaining within these narrow confines, in reality, there has been a proliferation of regional ordinances which, in many cases, has caused uncertainty and confusion[381].

Although the regulatory framework was complex and intricate, to say the least, it must be said that, in practice, during the most critical phase of the emergency, state, regional, and municipal regulations managed to coexist by aligning themselves with each other. The same cannot be said for the so-called Phase 2[382], during which one of the concerns that returned to the attention of state and regional decision-makers was to prepare measures aimed at the gradual reopening of economic activities in the face of a gradual slowdown in the pandemic, a context in which regional and state measures often found themselves in conflict. Symptomatic of the lack of clarity and coordination between the different levels of government was the case of Valle d'Aosta Regional Law No. 11 of 2021, which led to the Constitutional Court issuing a precautionary suspension[383].

This law, which aimed to dictate "Measures to contain the spread of the SARS-COV-2 virus in the social and economic activities of Valle d'Aosta in relation to the state of emergency," provided for the gradual easing of restrictions introduced to

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[381] There have been numerous and conflicting regional ordinances issued both in compliance with the legislation introduced at the state level and in relation to measures introduced in the territories of other regions; for a detailed analysis of regional interventions during the emergency period, see in particular Delledonne G. Padula C., *op.cit.*, who divide the regional ordinances adopted into four categories: firstly, those adopted even before uniform state legislation was introduced for the whole of the national territory – such as, for example, the ordinance of the Campania region of February 24, 2020, which prohibited meetings and demonstrations in order to prevent the spread of infection – there were then numerous ordinances aimed at introducing measures that were even more restrictive than those introduced at state level – This includes the Order of the President of the Regional Council of Veneto No. 33/2020, which, in order to prohibit gatherings of people, reinforced restrictions on movement within a certain distance, ordered the closure of public gardens and parks, and regulated the opening and closing times of food shops. In addition, numerous regions in the south introduced restrictions on entry into the region for those coming from the regions of northern Italy most affected by the virus.

[382] This term refers to the phase following the enactment of Decree Law 19/2020, during which the measures became less restrictive and one of the interests to be balanced against the public interest of health pursuant to Article 32 of the Constitution was the need to resume economic activity given the gradual easing of the epidemic, e.g. O.P.G.R. Veneto 43/2020 and 44/2020, which allowed travel to second homes owned by residents, and O.P.G.R. Campania 41/2020, which allowed those who had remained outside the region due to restrictions and had been unable to return during the first phase to return.

[383] The precautionary incident in direct appeals between the state and regions was introduced by Article 9 of Law No. 131 of 2003, which amended Article 35 of Law 87/1953. For the unprecedented, albeit not innovative, use of this instrument, see M. Rubechi, *Due "nuove" rondini ...fanno primavera? Considerations on recent trends in Italian regionalism,* in *Federalismi,* 10/2021;

promote the recovery of economic activities, even though this conflicted with state legislation, which had not yet taken a position on lifting the restrictions previously introduced.

To resolve the conflict and overcome the dispute, the Government decided to challenge the regional law, not only on the grounds of conflict but also on the grounds of a violation of the division of powers.

For the first time, with Order No. 4 of 2021[384], the Court suspended the contested regional law, considering that the conditions of *fumus boni iuris* and *periculum in mora* were met, noting in concrete terms the possible irreparable damage to the public interest and individual rights resulting from the application of that law[385]. The Court itself objects that 'the contested regional law, by overlapping with state legislation, dictated in the exercise of the aforementioned exclusive competence, exposes itself to the concrete and actual risk that the contagion may accelerate in intensity, due to the fact that it allows for measures that may be characterized as less rigorous; this is regardless of the content of the orders actually adopted'; based on the assumption that 'the manner in which the Covid-19 virus spreads means that any increase in risk, even on a local basis, is likely to irreparably compromise people's health and the public interest in the unified management of the pandemic at national level, which does not preclude regional diversification within the framework of loyal cooperation'.

There therefore appears to be a need for unified and uniform management throughout the territory in the face of a situation defined by the Court itself as "absolutely exceptional." This requirement is reflected in the subsequent ruling no. 37 of 2021, in which the Council ruled on the appeal directly, bringing the matter

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[384] The regional law in question provided for a list of activities permitted in compliance with safety protocols, a second series of activities permitted unless suspended by the President of the Regional Council as provided for in Article 2, paragraphs 11, 12, 14, 15, 16, and 24 (such as retail commercial activities, catering services, artistic and cultural activities, accommodation and tourist facilities, and cableways for sports or tourist-recreational use); finally, there was a series of activities permitted subject to authorization by the President of the Regional Council, as provided for in paragraph 9 of Article 2 (including sporting events and competitions); and also providing for the possibility for the Regional Council to suspend the safety protocols in force in the national territory in Article 4;

[385] A. Nania, *La sospensiva cautelare: dal conflitto di attribuzioni tra stato e regioni al giudizio sulle leggi (Precautionary suspension: from the conflict of powers between the state and regions to the judgment on laws),* in *Federalismi,* 2002

of pandemic management within the exclusive competence of the state for international prophylaxis under Article 117(2)(q).

This solution has been heavily criticized by legal scholars, who denounce, on the one hand, the forced interpretation of the text of the title of competence for international prophylaxis[386] and, on the other hand, the missed opportunity to clarify an incomplete division of competences that could deal with emergency situations characterized by demands for uniformity as opposed to the need for differentiated measures[387].

From an analysis of the legislation introduced by the Italian institutions during the pandemic emergency, we can therefore identify two fundamental critical issues *ex post*.

On the one hand, the legislation adopted by the government is open to criticism based on the excessive centrality it gives not only to the executive branch, but also to the Prime Minister as the key figure in the regulatory management of the emergency. This centrality is reflected in the dominance of monocratic acts adopted by the Prime Minister to deal with the crisis, the nature of which remains unclear given their regulatory content and the provision for parliamentary participation in their adoption, even though they are classified as administrative acts implementing measures provided for at the primary level by the decree-law.

The alteration of the system of sources and balance of power does not exhaust the critical issues that have emerged from this management, which are equally reflected in the division of powers between the State and the Regions as outlined in the 2001 Reform. Faced with a proliferation of central and regional commands, often of opposite sign, the Court, in a historic intervention, justified the centralization of

[386] B. Caravita, *The Court's ruling on Valle d'Aosta: like a scalpel in the butter of regional (legislative) powers,* in Federalismi, 2020; conversely, E. Lamarque, *Precautionary suspension of regional law by the Constitutional Court (Note to Constitutional Court 14 January 2021 no. 4),* in *Giustizia Insieme;* the author acknowledges the broadening of the concept since the 1990s, when it was mostly used for veterinary checks at the border, and, since the Court's ruling no. 5 of 2018 on compulsory vaccinations, this concept has come to include the prevention of the spread of human diseases, confirmed, most recently by a number of rulings handed down by the administrative courts during the pandemic (Calabria-Catanzaro Regional Administrative Court No. 841/2020; Sicily-Palermo Regional Administrative Court No. 1952/2020; Calabria-Catanzaro Regional Administrative Court No. 2077/2020; Council of State Opinion No. 735/2020).

[387] Thus M. Rubechi, *Due "nuove" rondini, op. cit.*

management precisely because of the emergency and absolutely exceptional nature of the current situation.

Faced with a Constitution that is in some ways deliberately silent and in others incomplete[388], emergency management in the Italian legal system remains without a precise and specific regulatory framework that could clarify the respective powers and competences of both the institutional bodies and the different levels of government that make up the Republic.

Although the reasons for this 'silence' can be traced back to a heavy historical legacy, the pandemic experience has shown us how the silence of the Constitution can nevertheless lend itself to possible centripetal drifts, even if justified by exceptional and emergency situations.

4. The management of Covid-19 in the federal state of Belgium

Another model of emergency management is that provided for by the Belgian Constitution, which, although it too is a legal system without express emergency provisions, like the Italian one, differs from it in certain characteristics deriving from the constitutional provisions themselves, which have had important repercussions in practical terms on the management of the Covid-19 emergency.

First of all, it is worth highlighting the numerous similarities between the Belgian and Italian constitutions.

Despite the absence of an express emergency clause regulating the distribution of powers between the different levels of government and the powers attributed to the body identified as responsible for emergency management, this can be inferred by interpretation from certain provisions of the Constitution itself. As indicated in the Italian case, the lack of express provisions does not mean a total absence of such provisions[389].

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[388] On the recent setbacks in the development of Italian regionalism, see L. Califano, I *nodi irrisolti del regionalismo italiano (The unresolved issues of Italian regionalism),* in *Cultura giuridica e diritto vivente (Legal culture and living law),* 10/2022.

[389] G. De Vergottini, *Diritto costituzionale comparato (Comparative Constitutional Law),* Padua, 2019;

The only express emergency regulation is in fact that relating to a state of war, as a result of which the executive can exercise legislative power through the enactment of a primary source, such as decree-laws[390].
In the following Article 105 of the Constitution, after establishing the principle of legality according to which the King has no powers other than those attributed to him by law, it is established that in exceptional cases, Parliament has the authority to allow the Government to adopt so-called special decrees. These are sub-primary sources that find their legitimizing source in the authorization law, which must contain precise indications regarding the matters on which the Government may intervene and the time within which it is authorized to do so[391].
The emergency regulations derived from certain constitutional provisions, which confirm the absolute centrality of the role of the executive, even in the Belgian case, are supplemented by a series of sub-primary sources through which the Government effectively exercises its prerogative to manage emergencies.
Among these, *the Arrêttés royal du 31 janvireer 2003 portant fixation du plan d'urgence pour les événements et situations de crise nécessitant une coordination ou une gestion à l'échelon national (Royal Decree of January 31, 2003, establishing the* emergency plan for events and crisis situations requiring *coordination or management* at the national level) is of particular importance, as it introduces an emergency plan aimed at establishing a unified federal management model for particularly extensive emergency situations. It provides for the possibility of initiating the 'federal crisis coordination phase' when one of the conditions outlined in the Arrêtté itself is met[392].

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[390] A prerogative which, according to Belgian constitutional practice, has been used more to respond to situations of political complexity in which Parliament found it difficult to fulfill its legislative function than to deal with situations of crisis or necessity in the strict sense;
[391] G. Milani, *The health emergency in comparative public law: Belgium's response to Covid-19,* in *DPCEonline,* 2/2020, p. 1167 ff;
[392] as prerequisites for the initiation of centralized emergency management, the law provides for the occurrence of a crisis situation extending to two or more provinces or to the entire national territory; insufficient resources available to provincial governments to deal with the crisis; current or potential presence of numerous victims; current or potential danger of serious effects on the environment or food production; current or potential threat to the vital interests of the nation or the essential needs of the population; need to coordinate the various administrative structures; need for general information to the entire population; see Royal Decree of January 31, 2003, published on February 21, 2003;

To complete the analysis, it is necessary to highlight a further constitutional provision that is potentially relevant to the regulatory management of emergency situations: Article 26 of the Constitution, which constitutes an express partial derogation from the general rule outlined in Article 187 of the Constitution, according to which constitutional provisions may not be suspended, either partially or totally, under any circumstances[393].

The second paragraph of Article 26 makes gatherings in open spaces subject to police control and compliance with police laws. Although this provision was originally intended solely to ensure the safe and free use of public spaces[394], following an extensive interpretation by the courts, it is now used to legitimize preventive restrictions on freedoms exercised on public land[395].

This regulatory framework was the basis for the measures adopted to deal with the Covid-19 pandemic emergency.

Based on the regulatory instruments used, two different phases of management can be distinguished: an initial phase based exclusively on ministerial Arrêttes containing restrictions to attempt to stem the impact of the epidemic, followed by a second phase based on two laws enacted by Parliament, whereby the latter empowers the King or the Council of Ministers to take the necessary measures to combat the spread of the virus.

First things first, on March 13, 2020, the government declared the start of the "federal phase of crisis coordination and management" based on the Arrêt regulating the state of emergency, introducing the first containment measures on a national basis[396] with legal basis in the police power provided for in Article 26 of the Constitution. This measure was followed by two further Arrêttes, one on March 18, subsequently replaced by the one issued on March 23, which differed from the

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[393] See S. Van Drooghenbroeck, *Article 187 of the Constitution,* in *Revue Belge de droit constitutionnel,* 2006;

[394] Y. Lejeune, *Belgian Constitutional Law: Foundations and Institutions,* Brussels, 2014;

[395] In this regard, see Cour de Cassation, January 20, 1879, and subsequently Conseil d'Etat, Section du contentieux, Arrêt n.80.282, May 18, 1999, Van Der Vick, Lecompte e.a.c. ville d'Anvers.

[396] With the Ministerial Decree of March 13, 2020, triggering the federal phase concerning the coordination and management of the COVID-19 coronavirus crisis, gatherings are prohibited and movement is restricted, schools and commercial activities are closed, and work is severely limited by a series of restrictions aimed at ensuring social distancing.

previous one in terms of the additional restrictions introduced[397] and the legal basis, which was partially different[398].

In view of the critical issues identified in this highly centralized management model favoring the central government at the expense not only of Parliament but also, and above all, of the federated entities, the second phase was launched with the promulgation of two different laws authorizing the Government by Parliament, which specifically indicate the prerogatives, limits, and scope of involvement of local authorities.

In particular, with the *Loi habilitant le Roi a prendre des mesures de lutte contre la propagation du Covid-19*, the government is empowered to intervene in the administrative regulation of the Council of State and other administrative courts in order to ensure the continuity of the administration of justice. The second *law* provides for a broader and more heterogeneous range of prerogatives of intervention attributed to the executive, which is empowered to adopt measures aimed at combating the spread of the virus, maintaining public health and public order, providing direct and indirect support for economic and financial activities, adopting measures to protect workers, and ensuring the proper functioning and continuity of the administration of justice.

These measures enacted by the legislature form the legal basis for the subsequent measures introduced through government decrees[399] in such a way as to ensure compliance with the principle of legality, which subordinates any restrictions on constitutionally guaranteed rights to eventualities provided for by laws expressing legislative power, in accordance with the 19th-century liberal tradition embodied in the Belgian Constitution.

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[397] The decree of March 18 specifies certain measures already introduced in the previous decree regarding commercial activities; it introduces a general ban on gatherings and limits the possibility of leaving one's home for reasons related to work, health, or to go to a commercial activity; it mandates teleworking and the closure of lower-level schools, with distance learning for higher-level schools and universities. The subsequent decree of March 23 reiterates the contents of the previous one, extending them for a longer period of time, and further specifies the commercial activities whose services continue to be guaranteed.

[398] The preamble to the decrees of March 18 and 23 identifies as its regulatory basis, in addition to the laws on police and civil security, the law on civil protection, as well as the opinions of the Assessment Unit established under the emergency plan.

[399] From March 27 to May 20, 2020, the Government adopted 22 decrees implementing the special powers granted to it, mainly aimed at ensuring the proper functioning of the administration of justice and measures to support the economy and health facilities.

As regards the division of powers between the different levels of government, it should be noted that the Belgian federal state is based on a rigid division of powers, only partly outlined in the Constitution, which refers to a special law for detailed regulation[400].

For the purposes of this discussion, it suffices to point out that neither the Constitution nor the special legislation defines the powers in the field of health protection and healthcare[401]. Following the intervention of the Council of State[402], it has been clarified that each level of government is responsible, within its respective competences, for defining strategies to combat health emergencies, without prejudice to the possibility of entering into cooperation agreements on common strategies.

Such mechanisms were also envisaged and put in place during the management of the pandemic. Although the pandemic was exclusively concentrated in the hands of the central government from the 'federal phase' onwards, the participation of federal entities in decision-making processes was nevertheless guaranteed. Particular reference is made to the provision of concerted mechanisms at the federal level based on the special participation of territorial representatives within the Security Council[403], whose meetings always preceded the adoption of the various ministerial decrees.

In light of this brief analysis, it is clear that the Belgian legal system, although lacking explicit constitutional provisions, has used all the instruments that

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[400] Special Law of August 8, 1980, on institutional reforms;

[401] Pursuant to Articles 127 et seq. of the Constitution, communities are responsible for language use and teaching in cultural subjects; the powers of the regions are not provided for in the Constitution, which refers to special legislation, pursuant to which regional powers are limited to land management and economic development; finally, the federal authorities have residual powers. The rigid division of powers, which does not provide for forms of cooperative federalism, is balanced by the possibility of collaboration between federal and federated authorities, provided for in formal and informal forums, to define solutions that are as widely shared as possible between the different levels of government; see M. Leoy, *Il federalismo belga,* in A. Pace (ed.), *Quale, tra i tanti federalismi,* 1977; F. Angelini, M. Benvenuti, *Il riparto delle funzioni (Blegio),* in R. Bifulco (ed.), *Ordinamenti federali comparati,* II, 2021; S. Depré, *La cooperation,* in F. Delpérée (ed.), *La Belgique federal,* 1994.

[402]See Conséil d'Etat, Section de législation, Avis n. 53932/AG, 27 August 2013; and Conséil d'Etat, Section de législation, Avis n. 53018/VR, 13 May 2013;

[403] Established in 2015, it is chaired by the Prime Minister and composed of the Ministers of Justice, Defense, the Interior, and Foreign Affairs. Other ministers and representatives of state administrations may also take part in ordinary meetings, while representatives of the regions and communities are not expected to participate.

existed prior to the pandemic which, even in the current extraordinary context, have made it possible to introduce the necessary measures in compliance with existing legislation, while ensuring the participation of local authorities in the preparation of the pandemic management strategy.

5. *The state of health emergency: the French case;*

The intrinsic transnational nature of epidemics in general, and the 2020 pandemic in particular, meant that several national states had to address and manage the consequences at the institutional regulatory level as well.

The French government adopted a regulatory model for managing the pandemic emergency that can be described as similar to the so-called Italian model from the substantive point of view of the measures adopted—i.e., the generalized closure of productive activities, restrictions on certain fundamental freedoms provided for and protected by both constitutions—but differs from the latter in terms of the instruments through which this management was implemented.

In fact, following an initial phase of intervention based on *decrees* issued by the government or the Minister of Health, France chose to take the path of strict legality, in keeping with its historical tradition, by enacting an *ad hoc* law establishing a *state of health emergency* with Law 2020- 290, which, on the one hand, provides for general regulations that can be used to deal with health emergencies, but, on the other hand, introduces a series of provisions specifically aimed at regulating the Covid-19 pandemic emergency - at the time - which derogate from the general regulations contained in the same law.

There was much criticism of this intervention, which can be traced back to two basic sources: on the one hand, it referred to the lack of need for such regulatory intervention, given that the French state already had a multitude of emergency clauses, found both in the constitutional text and at the primary regulatory level; on the other hand, the criticism focused on the excessive generality of the provisions contained in the law.

First of all, it is necessary to provide a brief *overview* of the French constitutional framework for emergency situations as an alternative model to the Italian model in which, as seen above, emergencies are not specifically and expressly regulated.

Reference is made in particular to the provisions of Articles 16 and 36 of the French Constitution.

Specifically, Article 16 establishes that in cases of emergency posing a serious threat to the institutions of the Republic, the independence of the nation, the integrity of the territory, or the fulfillment of international commitments, the President may directly adopt ordinances, with the sole preventive requirement being a series of consultations with the Prime Minister, the Presidents of the Assembly, and the Constitutional Council. This provision was also subject to numerous criticisms denouncing its similarity to the dreaded Article 48 of the Weimar Constitution; these criticisms found expression in the 2008 amendment aimed at introducing further limits to the prerogatives granted to the President in emergency circumstances. In particular, the possibility was introduced for the President of the National Assembly and the Senate, as well as sixty senators or deputies, to instruct the *Conseil constitutionnel* - after thirty days of exercising extraordinary powers - to verify whether the conditions to which the exercise of such powers is subject are actually met.

Another constitutional provision that is potentially relevant in an emergency is Article 36, which regulates and provides for a state of siege, which contemplates the possibility of transferring certain powers to the military authorities over all or part of the national territory in the event of war or armed revolt.

This framework is completed by the primary legislation contained in Law No. 55-385 of 1955 relating to *the état d'urgence*, which has also been widely used in recent times[404] due to the breadth and generality of its provisions. The state of emergency referred to in the 1955 law may be declared by the Council of Ministers in the event of an imminent threat to public order and for events that can be

[404] The regulations aimed at governing the 2005 banlieues riots and the series of Islamic terrorist attacks that took place in 2015 were brought back under the state of emergency, see R. Casella, *France after the Paris attacks: the declaration of a state of emergency and President Hollande's proposal for constitutional reform,* in *Nomos,* 3/2015;

classified as 'public disasters'; this is counterbalanced by the obligation to inform the National Assembly and the Senate without delay of the measures taken by the Government, which may request further checks and assessments.

Although the French regulatory system is a clear example of a legal system that is 'prepared' for the definition of emergency situations, the scale of the 2020 pandemic, given its severity and its potential to harm both individual and collective health, has prompted French institutions to intervene with *ad hoc* measures.
In particular, French pandemic regulatory management can be divided into two distinct phases, depending on whether they were implemented before or after the watershed date of March 23, 2020, when Law 2020-290 came into force.

The first measures were introduced through the Arretés Ministerials[405] of the Ministry of Health, which introduced restrictions on gatherings, meetings, and the closure of commercial activities, up to and including a general obligation to stay at home throughout the country. In this way, a few weeks later, a management intervention system was adopted that mirrored that prepared by the Italian government[406].

Further restrictive measures were issued by individual mayors in the exercise of their public order functions under *the Code général des collectivités territoriales*[407]; these measures were often challenged before the administrative courts, which annulled them in cases where the further restriction of rights was deemed unjustifiable in relation to the restrictions introduced at the state level.

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[405] for an in-depth analysis of the similarities between this instrument and the decree of the President of the Council of Ministers adopted in Italy, see M. Rubechi, The *decrees of the President. Study on the d.p.c.m., government regulations and decision-making dynamics,* Turin, Giappichielli, pp. 131 ff., 2022;

[406] Reference is made in particular to the Arretés published on March 4, 9, and 13, 2020, by which the Minister of Health progressively banned gatherings and meetings throughout the country, with the exception of those essential to the life of the nation; this was followed by the Arretés of March 14, which ordered the closure of businesses such as bars, restaurants, and shopping centers; the ban on movement, introduced on March 17, 2020, was introduced by means of a decree of the Prime Minister – Décret no. 2020-260, which prohibited people from leaving their homes except for essential reasons and urgent family needs. Furthermore, this decree initially provided for the possibility of leaving the home 'for health reasons' and allowed short trips in the vicinity of the home for physical activity and to meet the needs of pets. These latter provisions were censured by the Conseil d'Etat in Ordonnance no. 439674 of March 22, 2020. For a more complete overview of the measures introduced by the French government during the pandemic, see F. Gallaranti, *Fundamental freedoms put to the test by coronavirus. The management of the health emergency in Spain and France,* in L. Cuocolo (ed.), *Constitutional rights in the face of the Covid-19 emergency. A comparative perspective,* in *Federalismi.it,* Covid-19 emergency observatory, 2020;

[407] In particular, Articles L. 2212-1 and 2212-2;

Criticism of this system of intervention mainly concerned the failure to comply with the principle of legality, given the weak legal basis of the measures adopted by the French government[408], consisting of *the Codé de la Santé Publique*[409].

The French Public Health Code establishes a system of intervention at two different levels of government: at the central level, the Minister of Health is empowered to adopt any measure, through reasoned *decrees*, provided that it is proportionate to the risks and appropriate to the circumstances of time and place, in order to limit the consequences of threats to public health; in addition, the same Minister has the power to authorize the prefect with territorial jurisdiction to adopt measures to implement these *arrêttés,* subject to an obligation to inform the public prosecutor.

This system reflects the same contradictions found in Italian legislation: the excessive vagueness of the delegation contained in Decree Law No. 6, to which was added a blank delegation in favor of the Prime Minister and which can be found, in this provision, which likewise does not provide a list of measures that can be adopted to deal with situations posing a risk to public health. As in the Italian system, there is no adoption procedure that recognizes an equally important role for the Legislative Assembly.

In response to the criticism, the French institutional apparatus decided to provide an unprecedented legal basis for the measures introduced and that could be introduced from time to time to try to manage the pandemic emergency, thus distancing itself from the Italian model, which is based purely on executive legislative acts.

Law No. 2020-290 established *the état d'urgence sanitaire (state of health emergency)* in response to the accelerated legislative procedure provided for by parliamentary regulations, which allowed for the rapid approval and promulgation of the law[410].

Under the law, a state of health emergency may be declared by decree of the Council of Ministers, over all or part of the territory of the State, 'in the event of a

[408] Thus F. Gallaranti, *op. cit.*

[409] L. 3131-1.

[410] The parliamentary process for the approval of the bill began on March 18 in the Senate, reaching its final approval on March 23 and subsequent publication in the Journal Officiel on March 24, 2020;

health disaster which, by its nature and severity, endangers the health of the population'[411] .

It seems appropriate to analyze the scope of the legislation adopted from three perspectives in order to highlight the corresponding critical issues.

Firstly, the merit of the law was to list the series of measures that can be adopted by the government in the event that a state of health emergency is declared. In accordance with the principle of legality, the law contains a list of measures that can be adopted by the government[412] . However, fails to stem the tide of criticism regarding the excessive vagueness of the management powers entrusted to it, as the same law includes two closing clauses aimed at recognizing the Government's ability to adopt any measure that could make appropriate medicines available to patients and any other restriction on freedom of enterprise aimed at ending the health emergency[413]. The only provision [414] is a vaguely defined obligation on the government to report to the National Assembly and the Senate, which have the recognized right to request information for the purpose of evaluating the measures introduced.

Finally, it seems necessary to emphasize the element on which the criticism of the law in question is mainly based: the provisions contained therein are, on the one hand, intended to apply only to future health crises, since, on the other hand, a derogation is provided for in the case of the Covid-19 emergency.

The possibility of extending the state of health emergency introduced by the 2020 law is subject to parliamentary authorization within one month of its declaration, while Article 4 of Law No. 2020-290, by way of derogation from the previous provisions, provides that the state of health emergency declared in light of the current pandemic shall last for two months from the entry into force of this law.

Proceeding towards the conclusions of this brief analysis, it is therefore possible to emphasize that the presence of an *ad hoc* clause in the French

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[411] Art. 3131-12 Code de la santé publique, introduced by Art. 2 of Loi no. 2020-290;

[412] These are mainly measures already introduced at ministerial level, such as: a ban on the movement of people and vehicles, a ban on leaving the home except for necessary travel, compulsory quarantine or isolation for those infected, closure of public establishments, requisitioning of goods from personnel necessary to combat the epidemic, and price controls;

[413] Nos. 9 and 10 of Article L. 3131-15 of the Public Health Code;

[414] Art. L. 3131-13 Code de la santé publique, introduced by Art. 2 of Loi no. 2020-290;

constitution has not succeeded in tempering the conflicting dichotomies of freedom/security and limitations/principle of legality, traditionally present in any emergency context.
The French government, despite being equipped not only at the constitutional level but also at the primary regulatory level with provisions designed to deal with crises such as the one that actually occurred with the pandemic, nevertheless decided to intervene with a *newly* introduced regulatory instrument, whose innovative features can be traced back to an expansion of the executive's prerogatives that is not matched by a corresponding increase in the parliament's powers of control.

Numerous criticisms have been raised about the lack of necessity for this intervention[415], which some consider to be a mere political opportunity aimed at maintaining a firm majority and popular support[416]; it appears that the same results could have been achieved otherwise through an additional amendment to the conditions governing the state of emergency provided for by the 1955 law or by using the powers provided for in Article 16 of the French Constitution.

Although France has therefore chosen the path of strict legality, introducing measures through the regulatory instrument par excellence, it seems fair to conclude that the choice of parliamentary law cannot always remedy all the traditional discrepancies associated with an 'emergency government', such as centralization of the executive, marginalization of parliament, and regulatory uncertainty.

6. *Covid-19 pandemic: emergency or exception? The Spanish case*

Faced with a post-dictatorial legacy such as that of Franco, the Spanish Constituent Assembly decided to react in a diametrically opposite way to the Italian one, which chose to avoid emergency provisions in the constitutional text precisely because of the heavy and echoing legacy of the Weimar Constitution. In fact, the Spanish Constitution of 1978 provides for and regulates three different types of emergency

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[415] A. Gelblat, L. Marguet, *L'etat d'urgence sanitaire: la doctrine dans tous ses etats?,* in La *Revue des droits de l'homme,* 2020;
[416] C. Sartoretti, *La risposta francese all'emergenza sanitaria da Covid-19: Stato di diritto e Costituzione alla prova della pandemia,* in *DPCE online,* 2/2020, p. 1637 ff.

situations, identifying for each one the conditions, procedures, and related prerogatives recognized for dealing with concrete crisis situations, as a symptomatic reaction to the Franco regime[417].

The three different regimes provided for in Article 116 of the Constitution correspond to different emergency scenarios of increasing severity, each of which corresponds to a specific scope of prerogatives recognized by the executive and a more or less invasive role for Parliament.

However, concerns about the possible authoritarian drift that such clauses may entail are not entirely absent, as can be seen in the speed with which, a few years after the promulgation of the constitutional text, to Organic Law No. 4 of 1981, which provided a more comprehensive framework – in terms of prerequisites and procedural requirements – for these derogatory regimes: the state of alarm, the state of exception, and the state of siege.

The second paragraph of Article 116 regulates and provides for a state of alarm aimed at dealing with natural emergencies such as floods or cataclysms, health crises and the paralysis of public services essential to the community or the absence of basic necessities. Declared by decree of the Council of Ministers – on its own initiative or that of an autonomous president – the state of alarm may affect the entire national territory or part of it for a maximum duration of fifteen days, after which an extension is permitted with the prior authorization of the Congress of Deputies.

Among the various regimes governed by the Spanish constitution, this is the state characterized by the greatest breadth of powers reserved for the executive branch,

[417] At the beginning of the parliamentary debate in *the Constituent Assembly,* an amendment was tabled by the Communist Parliamentary Group proposing to remove the constitutional provision for a state of emergency due to a lack of specification of the circumstances that would justify its adoption (citing only situations attributable to natural disasters as possible cases); added to this ambiguity was that relating to the possible negative consequences that fundamental rights could suffer under such a regime. The totalitarian fear from which this proposed amendment stemmed was clear, but the amendment was rejected precisely because of the possible paradox that could arise from the absence of such constitutional provisions: in this regard, the founding father Gabriel Cisneros Laborda, a member of the Center Party, argued for the need to maintain the provision for a state of emergency because, if it were abolished, in emergency situations it would be necessary to resort to mechanisms that could potentially be even more detrimental to fundamental rights. For a detailed historical account of the Spanish constitutional debate, see M. Carrillo, *Diritto di eccezione e sistema costituzionale in Spagna di fronte alla pandemia da COVID-19 (The right of exception and the constitutional system in Spain in the face of the COVID-19 pandemic),* in *Costituzionalismo.it,* 2/2021.

which is outlined as the sole decision-maker and has the power to introduce measures aimed at restricting fundamental rights[418] through decrees that must simply be communicated to the Chamber.
Although the state of alarm is characterized by the absolute centrality of the role of the executive, it should be emphasized that the latter cannot go so far as to suspend fundamental rights, limiting its prerogatives to a possible restriction of these in order to deal with the situation giving rise to the emergency.

The possibility of suspending fundamental rights is instead provided for in cases where a state of emergency is declared, which, governed by the third paragraph of Article 116 of the Constitution, provides that it be declared by the Chamber of Deputies, at the request of the government, "*when the free exercise of the rights and freedoms of citizens, the normal functioning of democratic institutions and public services essential to the community, or any other aspect of public order, are so seriously compromised that the exercise of ordinary powers proves insufficient to* restore *them*"[419]. This is an exceptional regime aimed at regulating situations in which there is a serious disturbance of public order, understood as the constitutional order, which cannot be restored using ordinary powers[420].
When authorizing a state of emergency, Congress must necessarily indicate its effects, the amount of financial penalties, its territorial scope, and its duration, which may not exceed 30 days, except in the event of an extension.
The restoration of the role of Parliament in this case corresponds to a greater scope of the prerogatives of the executive, which, in order to meet the needs related to the peculiarity of the current situation, may adopt measures suspending various

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[418] Under Article 11 of Organic Law No. 4 of 1981, the Government is authorized to place restrictions on the freedom of movement or stay of persons or vehicles in certain places and at certain times, to carry out temporary requisitions of goods, to impose compulsory personal services, to temporarily occupy industries, companies, or premises, to rationalize the consumption of essential goods, and to impose orders necessary to ensure the functioning of services involved in a collective strike. Article 12 provides for the possibility, in the event of a health emergency, for the competent authority to issue measures provided for by legislation on the fight against infectious diseases.
[419] Article 13 of Organic Law 4 of 1981;
[420] V. Piergigli, *The Covid-19 emergency in Spain and the declaration of the estado de alarma. Repercussions on the institutional system and the rights regime,* in *DPCEonline,* 2/2020;

fundamental rights within the terms established by Article 55 of the Constitution and by organic law[421].

Finally, the fourth paragraph of Article 116 of the Constitution regulates the state of siege declared by the Chamber of Deputies by an absolute majority, at the request of the government, *"when an insurrection or act of force against the sovereignty or independence of Spain, its territorial integrity or its constitutional order occurs or threatens to occur, which cannot be resolved by other means"*[422]. The letter of the law itself makes it clear that a state of siege has been identified as *the last resort*[423] of the system because, in addition to allowing for the maximum suspension of fundamental rights[424], it implies militarization in the management of situations that pose a risk to public order. The Government, as the body responsible for military and defense policy, will assume all the powers provided for by Organic Law No. 4 of 1981 and will designate the military authority which, on the basis of its directives, will oversee the implementation of the measures adopted[425].

Faced with such a vast array of clauses aimed at regulating emergency situations, the government, in response to the exponential increase in Covid-19 infections, decided to intervene by declaring a state of emergency pursuant to the second paragraph of Article 116 of the Constitution with Royal Decree 463/2020 for the second time[426] in Spanish constitutional history.

In implementation of the Decree, there were numerous government interventions aimed at severely restricting certain fundamental rights such as freedom of assembly, movement, and religious worship, as well as various economic freedoms, which were severely restricted due to the closure of activities not considered essential. In this way, Spain adopted the line of intervention recently inaugurated by the Italian Conte government.

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[421] Articles 16 to 24 of Organic Law 4/1981

[422] Article 32 of Law 4/1981

[423] C. Guerrero Picò, *Spain,* in P. Passaglia (ed.), *Emergency powers and derogations from the principle of legality,* 2011.

[424] All rights listed in Article 55 of the Constitution may be suspended, i.e., those that may be suspended in the event of a declaration of a state of emergency, in addition to the legal guarantees for detainees provided for in Article 17(3) of the Spanish Constitution.

[425] Article 33 of Organic Law 4/1981;

[426] The only precedent that led to the application of Article 116 of the Constitution and, in this case, to the declaration of a state of alarm, was caused by a strike by air traffic controllers in December 2010, which resulted in the interruption of air traffic;

Although it therefore appears that the measures introduced, even though they severely restrict fundamental rights, have constitutional coverage both in terms of *modus* and in terms of procedure, as the relevant constitutional provision provides not only for the individual restrictions of fundamental rights, but also for the methods of parliamentary control[427], there was also considerable controversy in Spain about the failure to comply with constitutional provisions in the management of the pandemic crisis.

The critical issues raised mainly concerned two fundamental arguments: on the one hand, there was opposition to centralized management at the expense of regional autonomy, with the regions claiming a margin of intervention or at least a space for inclusion in decision-making processes, given the particular form of autonomy that exists in Spain[428]; on the other hand, criticism was raised regarding the type of state of emergency invoked, given the excessive length of the restrictions introduced – in view of a fourth extension of the state of alarm ordered by the Chamber – it no longer seemed appropriate or correct to act within the prerogatives provided for by the state of alarm invoked and declared, but rather to declare a different regime of state of emergency under which, with Parliament more involved in decision-making processes, it would be possible to suspend certain fundamental rights.

Proceeding in order, with regard to the excessive marginality of the role reserved for the autonomous communities during the management of the pandemic, it should first be emphasized that the Spanish Constitution outlines a form of regional autonomous state, thus placing itself in an intermediate position between the classic forms of decentralized state such as federalism and regionalism[429],

[427] F. Gallaranti, *Fundamental freedoms put to the test by coronavirus. The management of the health emergency in France and Spain,* in L. Cuocolo (ed.), *Constitutional rights in the face of the health emergency. A comparative perspective,* in *Federalismi.it, Covid-19 emergency observatory,* 2020.
[428] On this point, see Chapter III § 3;
[429] E. G. Reguera, *Experiences and prospects of regionalism in Spain,* 2006; M. Manganaro, *The evolution of differentiated regionalism in light of constitutional reforms. Some observations on this point, in comparison with the territorial model in force in Spain,* in *consultaonline,* 3, 2016; on Spanish regionalism, see J. Ruiperez Alamillo, *On the nature of the State of the Autonomies,* in *Revista de Estudios Politicos,* 81/1993; T. Font y Llovet, *The process of 'federalization' in Spain: administrative organization,* in *Ist. Federalismo,* 1, 2000; R. L. Blanco Valdes, *Los rostros del federalismo,* Madrid, 2012; E. Aja, *Estado autonomico y reforma federal,* Madrid, 2014.

regulating a division of powers that is strongly favorable to the Autonomous Communities, including the areas of hygiene and health[430].

Before the government declared a state of emergency, pandemic management measures were taken within each community through acts of *the Consejeros de Salud (Health Councilors),* such as *orders and resolutions,* based on Organic Law No. 3/1986 and Article 26 of Law No. 14/1986, respectively[431]. These acts created a state of uncertainty and confusion throughout the country, as they introduced measures of varying degrees of restrictiveness within their respective territories.

Following the declaration of a state of emergency throughout the country, Decree 493/2020 proclaimed the Government as the competent authority for management, and in their respective areas of responsibility, the Ministers of the Interior, Health, and Transport. No provision was made for cooperation between these authorities and the CA authorities, which are exclusively reserved limited power to propose the introduction of measures, while no formal involvement in the adoption phase of the same was provided for.
This absence, "far from being an oversight"[432], would rather represent an attempt to avoid possible negative repercussions arising from the difficulty in maintaining

[430] Under Article 148 of the Spanish Constitution, the matters for which the Autonomous Communities may assume competence within the scope of their statutes are: self-organization of government institutions, economic order, urban planning, housing and public works, local transport, agriculture, livestock, forests and forest improvements, environmental protection; hydraulic systems, irrigation systems, management of thermal springs and water sources, fishing, hunting, local markets, crafts, museums, libraries and conservatories, artistic heritage, support for culture and research, tourism, sports, leisure, social assistance, health and hygiene, local police, etc. As analyzed in greater depth in Chapter III above; healthcare, considered as a whole, is divided between the powers of the central government and those of the autonomous communities: Article 149 of the Spanish Constitution assigns responsibility for foreign healthcare, pharmaceutical legislation, and basic healthcare legislation to the state, while Article 148 assigns general responsibility for "hygiene and healthcare" to the autonomous communities. Through this system of constitutional division, the Spanish healthcare system is highly decentralized, as the autonomous communities are able to establish their own local healthcare services and are responsible for managing the facilities in their respective territories. On the other hand, the central government is responsible for coordinating these systems. The Spanish healthcare system is analyzed in Chapter III, §3.3.
[431] Law No. 3 of 1986 only provides that, in order to control communicable diseases, the health authority may take appropriate measures to control patients, people who have been in contact with them, and other measures deemed necessary in the event of a communicable risk. Article 26 of Law No. 14 of 1986 provides that, in the event of a suspected health hazard, the health authorities have the power to take the measures deemed appropriate, including the exercise of certain activities, the closure of certain businesses, and any other measure considered "health-justified."
[432] Thus F. Gallaranti, *op. cit.*

the spirit of collaboration between the State and the Autonomous Communities, which is absolutely necessary to deal with a major emergency, not only at the state level, but even at the global level.

It should be noted that the role of the autonomous regions was restored during the so-called *'descalada'* phase, in which the government opened up to greater involvement of the communities in defining the progressive easing measures, which, according to the plan prepared by the executive, were to take place gradually and asymmetrically, taking into account the epidemiological conditions of the respective territories[433].

The controversy surrounding the appropriateness of declaring a state of emergency rather than a state of alert was not without consequences. The opposition[434], leveraging the arguments of the lack of involvement of the Autonomous Communities in the implementation of the measures, as well as the marginal role assigned to Parliament in this regard and, finally, the effective suspension of fundamental rights – instead of the permitted limitation – decided to appeal to the Spanish Constitutional Court.

The provisions challenged were considered to violate, on the one hand, Article 116 of the Constitution, insofar as they introduced measures falling within and provided for in the different concept of a state of emergency referred to in the third paragraph, and, on the other hand, Article 55 of the Constitution, in that these measures constituted an example of the suspension of fundamental rights, rather than the 'restriction' permitted under a state of alarm.

Rather than delving into the dangerous theoretical debate about the distinction between the notions of "restriction" and "suspension"[435] of fundamental

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[433] Order of May 3, SND/387/2020, "regulating the process of co-governance with the autonomous communities and cities of Ceuta and Melilla for the transition to a new normality," published in the Official State Gazette No. 123 of May 3, 2020.

[434] In particular, more than fifty deputies from the Popular Party Vox in the Congress of Deputies filed an appeal of unconstitutionality against the provisions of Decree 463/2020 relating to the declaration of a state of alarm; the subsequent Decrees 465/2020 and 487/2020 extending the state of alarm; and against Order SND/298/2020 containing exceptional measures relating to funeral ceremonies to limit the spread of infection. For an examination of the ruling, see A. M. Russo, *"Alarm" or "Exception"? The Spanish Constitutional Court upholds the unconstitutionality of the government's anti-pandemic measures,* in *Diritti Comparati,* 2021.

[435] In this regard, Constitutional Court ruling no. 83/2016, in the context of an appeal for protection lodged against the declaration of a state of emergency following the strikes of 2010 "*Unlike a state of exception or war, the declaration of a state of emergency does not allow for the suspension of*

rights as a distinguishing criterion for the prerogatives that can be exercised in different states of alarm and emergency, the Constitutional Court decided to articulate its partial acceptance ruling by arguing about the effects and concrete scope of the Covid-19 pandemic crisis.

According to the Constitutional Court, the following measures adopted to deal with the emergency were – at least in abstract terms – fully in line with the constitutional provisions of Article 116(2). However, what caused a 'distortion' with respect to the constitutional provisions was rather the scope of the pandemic emergency which, in factual terms, went beyond the mere 'health emergency' envisaged as a prerequisite for declaring a state of alarm, causing detrimental effects on public order and thus creating a context in which a declaration of a state of emergency would have been necessary, rather than an extension of the state of alarm.

As a result of this decision, the measures prohibiting free movement and allowing the Minister of the Interior to close roads for public health reasons, as well as the possibility for the Minister of Health to extend or modify restrictive measures on commercial activities, are therefore annulled.

However, the question of the violation of other fundamental rights such as freedom of worship, the right to strike, the right to conduct business, and the right to education was rejected, on the grounds that these rights had simply been restricted as a result of the limitations introduced by the government and that the limits on the

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any fundamental rights (contrary to Article 55, first paragraph, of the Constitution), but only for the adoption of measures that may involve the limitation or restriction of their exercise. In this sense, the measures that may be adopted include the limitation of the movement or stay of persons or vehicles in certain places or their subordination to certain requirements; temporary seizures of all types of property and the imposition of compulsory personal services; the temporary occupation of industries, factories, laboratories, farms, or premises of any kind, with the exception of private homes; the limitation or rationing of services or the consumption of basic necessities, the adoption of orders necessary for the supply of markets and the functioning of the services of production centers affected by a paralysis of essential services for the community in the event that minimum services are not guaranteed; and, finally, the intervention of companies or services, as well as the mobilization of their personnel, with the aim of ensuring their functioning, with the applicable legislation on mobilization being applicable..."; However, although this ruling constitutes an important precedent on the subject of states of alarm and states of emergency, the Constitutional Court refrains from delving into the merits of the distinction between suspension and restriction of rights, limiting itself to setting out the measures that may be adopted pursuant to Article 11 of Organic Law 4/1981. See, in this regard, M. Carrillo, *Right of exception and constitutional system in Spain in the face of the Covid-19 pandemic,* in *Costituzionalismo.it,* 2/2021.

prerogatives granted to the executive branch during a state of emergency had therefore been respected.

7. *Concluding remark;*

The recent pandemic experience is, to date, the event that has most tested the European Union and its member states. This test was reflected, on the one hand, in the resilience of the organizational structures of the nations' health systems and, on the other hand, in the ability of legal systems to cope with an unprecedented emergency that required accelerated intervention by political institutions while maintaining compliance with constitutional provisions regarding fundamental rights. on the other hand, in the ability of legal systems to cope with an unprecedented emergency that required accelerated intervention by political institutions while maintaining compliance with constitutional provisions concerning fundamental rights, but also the division of powers defined in complex (i.e., regional, such as Italy and Spain) and federal (such as Belgium) states, ensuring the participation of representatives of all the different levels comprising the individual legal system.

As is typically the case in emergencies, these requirements are at odds with the inherent characteristics of emergency situations.
In light of this, an attempt has been made to propose an analysis of regulatory strategies adopted by different EU states based on different constitutional models, verifying whether the establishment of emergency management procedures at the constitutional level was relevant and, if so, to what extent, based on compliance with the principle of legal reserve as a guarantor of fundamental rights in the face of state power, as well as the principle of collaboration that permeates the division of powers between the different levels of government in composite states.

This led to an analysis of the emergency regulations of the French state, traditionally known for its emergency-oriented constitution. However, despite the existence of various constitutional and legislative provisions aimed at regulating crisis situations, France chose to introduce ad hoc legislation in anticipation of a

state of health emergency, containing provisions relating to hypothetical health crisis contexts *in genus* derogated from provisions contained in the same law, which at the same time introduced ad hoc regulations for the pandemic situation at the time.

There has been much criticism of this choice, which, while respecting the separation of powers, has chosen to privilege the role of the Legislative Assembly, focusing on the futility of such regulatory intervention.

Another example of constitutions containing express emergency regulations is the Spanish Constitution, which, in Article 116, provides for a state of alarm, a state of emergency, and a state of siege, each of which corresponds to more or less extensive prerogatives of the executive and relative margins of intervention by Parliament, given the difference in the conditions – in terms of severity – to which their activation is subject.

Although the Spanish Constitution already provided for this differentiation, in this case too, the numerous controversies surrounding the excessive attribution of powers to the executive, the marginalization of the role of Parliament, and the minimal involvement of the Autonomous Communities led the *Constitutional Court* to declare the decision to declare a state of alarm partially illegitimate, considering the different regime of a state of exception to be more appropriate in some respects.

Among the constitutional texts that expressly regulate emergency situations are those of Italy and Belgium, where, in the absence of specific constitutional provisions, emergency regulations can be derived from certain principles contained therein. In particular, the extraordinary possibility for the executive to exercise legislative power through acts having the force of law in emergency situations, as well as the role of parliaments in declaring a state of war.

In both of these legal systems, emergency regulations were initially based on a series of secondary acts issued exclusively by the head of the executive branch and, subsequently, in a second phase, on primary legislative acts that provided a list of possible measures that could be taken to deal with the crisis.

Although Italy had no constitutional provisions governing emergency situations, we can therefore say that the provisions from which certain principles

can be derived, combined with the primary legislation specifically dedicated to this, made it possible to set up a regulatory system for managing the emergency which, on the one hand, allowed for compliance with fundamental constitutional provisions to be maintained and, on the other, established the management model on which most Member States then based their response.
Although not without doubts and criticism, the Italian model has been the basis on which the entire community of European national states has built its regulatory strategy against the pandemic.

Faced with individual management plans drawn up at national level, the European Union attempted to introduce coordination measures to standardize the regulations introduced by individual countries. However, this aspiration was hampered by a severely limited scope of competence, both in terms of health protection regulations and emergency contexts. The EU took on a leading role in the second phase of the pandemic and in the final phase of normalization, phases in which the EU, with its strong economic powers, made itself indispensable with its ' ' aid for the recovery of medical devices, incentives for vaccine research, and, finally, a series of economic aid packages for member states.

To draw conclusions from this brief analysis of the regulatory methods through which the various legal systems have attempted to propose emergency management models, it seems possible to arrive at some important reflections, which will be developed in the concluding section of this paper.
It is both obvious and essential to affirm the expansive potential of the right to health, a need for collective protection which, although not theoretically capable of overwhelming the entire system of fundamental rights, has recently been proven in practice that, in the name of protecting this right to health, we may witness a widespread compression and limitation not only of the constitutional prerogatives recognized to citizens, but also of the institutional and constitutional balance.
A reaction that can be found in all the legal systems analyzed so far seems to be that of absolute centrality of decision-making at the central level, and therefore to the detriment of those legal systems characterized by the absence of pluralism, but also at the government level, to the detriment, this time, of the system of separation of powers and the role of parliament.

A dystopian scenario that leads us to reflect on the intrinsic value of substantive protection over organizational dimensions, and on the role of the central state compared to that of individual territories.

CHAPTER V

CONCLUDING REMARKS: THE INSTRUMENTS FOR IMPLEMENTING THE RIGHT TO HEALTH AND THE ROLE OF THE NATIONAL STATE

SUMMARY: 1. The instruments for implementing the right in the current legal context. – 2. The national state and territorial health organization: the essential levels. – 3. The role of the state and the financial conditionality of the right to health: the minimum core of the right. – 4. The national state and international organizations in the protection of rights: between transfers of sovereignty and emergency situations. – 5. The role of the state: guardian of the "hard core" of the right.

1. *The instruments for implementing the right in the current legal context*

As we have attempted to highlight in the first chapter of this thesis, the key point around which the paradigm of health protection is structured is represented by the historical transition from liberal ideology to social-constitutional ideology. This transition marks not only a historical and ideological change from the point of view of the protection of fundamental rights – understood in quantitative terms – but can and must also be appreciated from an institutional point of view, as this scenario represents the most innovative aspects compared to the past.

I believe it is appropriate to start from this point in order to articulate the summary considerations that follow in the following pages. Placing the analysis of the subject of the research, namely the right to health, in this specific historical context, it is necessary to emphasize how the implementation of the tasks assigned to the state – as a consequence of the birth of the welfare state – determines the proliferation of centers of government. This proliferation is appreciable both from a sub-national and a supra-national point of view, made necessary by the global dimension that health has come to assume.

Following a line of reasoning in line with diachronic regulatory development, it can be said that, in parallel with its affirmation as a fundamental right, it has become clear that the effectiveness of the protection of the right to health depends directly on the establishment of a healthcare organizational

apparatus responsible for the provision of healthcare services. The necessary existence of an organizational structure, as has been noted, implies the structuring of a system of links between the central state and local authorities in order to optimize the provision of services capable of satisfying the ambivalent need to satisfy individual interests relating to a specific territorially limited situation, which is counterbalanced by the equally indispensable guarantee of uniformity in the protection of the right to health. In addition to this innate need to balance uniformity and differentiation, it has become clear—with particular fervor in recent decades—that the right to receive healthcare services brings with it an equally inevitable and inherent need for balance, insofar as the establishment of a system for providing such services involves the expenditure of public money, given the universal nature of the Italian National Health System.

On the other hand, looking at the 'global' dimension in which institutions operate, it is considered necessary to enhance the recent need that permeates today's right to health. An object of protection that can no longer be confined to the different and fragmented national legislations requires, in fact, a homogeneous transnational framework, both because of the transnational nature of the risks inherent in it—such as epidemics and pandemics—and because of the global nature that permeates the entire contemporary world society.

This scenario is becoming increasingly necessary due to the loss of the exceptional nature of health emergencies, which, as has recently been demonstrated, are indeed recurrent in current events.

This complex reality reflects a paradigm regarding the role of national states which, at first glance, appears to be receding in the face of demands for autonomy from local authorities and the transfer of sovereignty to supranational bodies.

However, based on a comprehensive reading of the context under discussion, it is essential to analyze the health emergency context in which national states found themselves operating during the recent COVID-19 pandemic. This dystopian scenario has had consequences not only for the strict organizational structure of healthcare facilities, but also offers valuable insights into the role of the national state, which has taken on the leading role in pandemic management, to the detriment

of the autonomy attributed to regions, local authorities, and supranational organizations.

In light of the above considerations, this concluding section will attempt to offer a summary reflection on the nature of the role of national states in the substantive and service-based protection of the right to health.

This role is proposed as an evolution of the traditional role of absolute guardian of rights but, as we will attempt to demonstrate, it stems from this.

2. *The national state and the territorial organization of healthcare: essential levels*

As we attempted to highlight in the first chapter of this thesis, the key point in the structure of the health protection paradigm is represented by the historical transition from liberal ideology to social-constitutional ideology. This transition marks not only a historical and ideological change from the point of view of the protection of fundamental rights – understood in quantitative terms – but can and must also be appreciated from an institutional point of view; indeed, the institutional apparatus appears to be more innovative than in the past.

In accordance with the constitutional provision aimed at recognizing the right to health and proclaiming its character as a "fundamental right" in its dual dimension of individual right and collective interest, the Constituent Assembly distances itself from the "attitude of sovereign indifference"[436] typical of the previous liberal era.

[437]The wording relating to the right to health was the subject of numerous debates in the doctrine of the time, relating, on the one hand, to the determination of the

[436] See also R. Ferrara, *The right to health: constitutional principles,* in R. Ferrara (ed.), *Health and Healthcare,* in Treatise on Bio-law, S. Rodotà – P. Zatti (eds.), Giuffrè editore, 2010. According to the author, 'the system of principles and values of the rule of law was (in some ways) detached from – and indeed incompatible with – any project aimed at ensuring legal protection for the subjective situations of citizens (now referred to as persons) and, in particular, those that coalesce, to a moderate extent, around the right to health. The right to health was, quite simply, something that did not exist, i.e., a value that was not even conceivable in abstract terms as such in the context of the bourgeois state model."

[437] R. Ferrara, *The right to health: constitutional principles, Health and Healthcare,* in Stefano Rodotà, Paolo Zatti (eds.), *Treatise on Bio-law,* Giuffrè publisher, 2010; which emphasizes how

different legal situations attributable to it and, on the other, to the very nature of the rule, since it was not possible to identify *at first glance* whether it was prescriptive or programmatic in nature. The different legal formulations based on the provisions of Article 32 of the Constitution can be summarized in the dichotomy between the subjective dimension of advantage and the objective-collective dimension relating to the object of protection of the right[438] .

Although it manifests an evolved institutional political attitude that distances itself from historical precedents, the constitutional provision on health does not allow us to affirm an absolute break with liberal ideology.

It is precisely in this objective context that it is possible to identify the line of continuity between the constitutional text and the previous liberal tradition, insofar as the provision does not exhaust its scope in the provision of subjective positions of advantage but at the same time requires the legislator to prepare 'internal public order policies' aimed at giving effect to the right in question, thus recalling the traditional interventionist spirit of the state[439].

In this sense, today's institutional dimension, known to us as healthcare organization, seems to originate from the apparatus—albeit embryonic—adopted in the liberal era.

Article 32 of the Constitution has long been "archived as a programmatic constitutional norm incapable of establishing, in itself, subjective legal situations that can be directly used before the courts," attributing the distinction of its programmatic-prescriptive character to the dual dimension inherent in the provisions of Article 32: namely, placing the latter in the context of relations between private individuals or in vertical relations between citizens and public administration; see C. Mortati, *La tutela della salute nella costituzione italiana (Health protection in the Italian Constitution),* in *Riv. Infort. Mal. Prof.,* 1961, I; B. Pezzini, *Constitutional principles and politics in healthcare: the contribution of constitutional jurisprudence to the definition of the social right to health,* in C.E. Gallo, B. Pezzini, *Current profiles of the right to health,* Milan, Giuffrè, 1998.

[438] A dichotomy traced back to the metaphor of the two-faced Janus, where it was considered possible to identify in Article 32 of the Constitution a situation of subjective right accompanied by the provision of a legal situation attributable to a legitimate interest; thus A. Vignudelli, *il rapporto di consumo,* Maggioli, Rimini, 1984; on this point*, see* R. Ferrara, *Salute (diritto alla) [Health (right to)]*, in *Digesto delle Discipline pubblicistiche [Digest of Public Law]*, 4th ed., Turin, UTET, 1997. 2

[439] "Health and its protection are not resolved and exhausted, as already seen, in the promotion of legal situations of individual advantage, but also postulate, in line with the interventionist tradition of the rule of law, the mobilization of appropriate and necessary internal (and international) public order policies capable of acting positively on the protection of situations of meta-individual, i.e., collective advantage." according to R. Ferrara, *Right to Health: Constitutional Principles,* op. cit.

Although in an evolutionary sense and consistent with the values of the new constitutional charters[440], the healthcare-organizational profile seems to stem from the same need, already felt in previous eras, to protect the health of the community. A need that, if at first it was expressed exclusively through the provision of containment measures and the promotion of health and hygiene standards by an apparatus identified as a branch of the Ministry of the Interior, today this structure is organized hierarchically and enjoys full autonomy[441].

This hierarchy is headed by the Ministry of Health and is based on a territorial-regional dimension, thus supporting the further innovation brought about by the 1948 Constitution, whose pluralistic essence is further confirmed by the multitude of institutional centers that characterize the regional model.

As is widely known, the regional model was reformed in 2001 through a reform aimed at giving greater room for maneuver to territorial autonomies which, becoming holders of legislative power, moved from the role of mere implementing-administrative subjects to become co-holders of legislative power.

This panorama, rich in institutional and legislative actors, also – and perhaps above all – has an impact on the healthcare sector, which is regulated by both state and regional legislation in accordance with the provisions of the previous ordinary legislation relating to the National Health System.

Any reflection on the structure of the relationship between the state and local authorities in the field of health protection must necessarily start from the provisions of Article 117 of the Constitution, as amended by the Constituent Assembly in 2001.

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[440] On this subject, see C. Schmitt, *The Tyranny of Values,* Milan, Adelphi, 2008.

[441] Reference is made in particular to Law No. 2248 of 1888, whose provisions on the organizational structure of healthcare were confirmed in the subsequent Law No. 5849 of 1888. In light of these regulations—as analyzed in greater detail in Chapter I, § 2—the highly hierarchical healthcare structure was headed by the Minister of the Interior, who oversaw a territorial supervisory organization consisting of the Higher Health Council, the Provincial Health Councils, and the District Health Councils. on this subject, see F. della Peruta, *Public Health and Health Legislation from Unification to Crispi,* in *Historical Studies,* 4/1980, pp. 713 ff.; R. Ferrara, *Health (*right to), in *Dig. Disc. Pubb.;* vol. VIII, 1997, UTET; M. Di Simone, *Health Policies in Italy from Crispi to Giolitti. Research Paths in the Papers of the Central State Archives,* in *Population and History,* 1/2002, p. 143 ff.; G. Ognibeni, *Health Legislation and Organization in the Second Half of the Nineteenth Century,* in M.L. Betri, A. Gigli Marchetti (eds.), *Health and the Working Classes in Italy from Unification to Fascism,* Angeli, Milan, 1982, 583 ff.; G. Vicarelli, *The Roots of Health Policy in Italy, Society and Health from Crispi to Fascism,* Il Mulino, Bologna, 1997;

This provision seems to reflect the complexity of the issue under discussion, starting from the close interrelationship between the substantive protection of the right to health and the provision of healthcare organizational structures. It appears that both of these are recognized in the division of powers between the State and the regions.

As we have attempted to argue in this paper and as we have had occasion to repeat in the preceding lines, it seems safe to say that the central role of the national state in the substantive protection of the right to health is widely recognized, while, as far as healthcare organization is concerned, it is equally possible to affirm that the latter is more specifically relevant to the competence of the regions. The choice made by the legislator in 2001 is based on the need to guarantee the regions a margin of autonomy in the management of their own healthcare organization, which is functional to organizational adaptation to the needs of specific territories[442].

This need can be recognized as an expression of both the principle of subsidiarity—insofar as it assigns the management of certain administrative services to the level of government closest to the citizens—and the principle of equality in its substantive dimension, which requires differentiated treatment to meet dissimilar needs.

Faced with an organizational scenario in which the central state appears to be losing its central role, it is indeed possible to identify different instruments – provided for by the Constitution itself – aimed at affirming the preeminent role of state legislation even in a sector of concurrent competence such as health.

Reference is made in particular to two different titles included in the division of powers under Article 117 of the Constitution, namely the determination of the essential levels of services referred to in letter m) and the subject of health protection itself, included in the third paragraph of the same article.

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[442] This orientation is supported by a series of rulings by the Constitutional Court itself, which were issued immediately after the 2001 reform came into force. Particular reference is made to the rulings relating to the relationship between the establishment of fundamental principles (which are the responsibility of the state) and detailed regulations (regional) in the field of health protection legislation as a concurrent competence under Article 117(3) of the Constitution. In particular, we note ruling no. 329 of 2003, in which the judges of the Court affirm the need to implement regulations concerning fundamental principles in the field of health protection through legislative acts that are no different from the law; or judgment no. 510 of 2002, which recognizes the possibility for regions to derive the regulation of fundamental principles even within the framework of previous legislation, without having to wait for the adoption of a specific subsequent regulation by the State.

Limiting the analysis to this second title of competence, it can be said that through the need for a state law aimed at "defining the content of the law"[443], the constituent assembly expressed its desire to guarantee the role of the central state in protecting the substantive dimension of the law[444], thus relegating the organizational dimension to detailed regional regulation.

However, it can be said that the powers reserved by the Text to the State in the field of health protection are not limited to establishing the fundamental principles in this area, but extend to the recognition of an important role in the field of healthcare organization. Due to the close connection between the substantive and organizational dimensions of the right to health, it was deemed necessary to ensure that the State also plays a role in the healthcare sector, insofar as the organizational dimension is as important for the effective protection of the right as it is for the substance of the right itself[445].

This requirement is met by the provision of the second paragraph, letter m) of Article 117 of the Constitution, which identifies the determination of essential

[443] "It is useful to distinguish between the regulation of the law and the organization of the services necessary to satisfy it. As regards the former, as has been said, this is the responsibility of state law, first and foremost in consideration of the principle of equality, which requires that the qualification of the right to health be identical for everyone throughout the national territory." Thus, A. Pioggia, *Diritto sanitario e dei servizi sociali (Health and Social Services Law),* Giappichelli, Turin, 2024; the author attributes this state task to the principle of equality rather than to the division of powers, dividing the substantive dimension of protection from the organizational dimension and stating that "if it is the principle of equality that imposes a national law, this law will have the competence to define in general and in detail what the right to health consists of; if, on the other hand, we base ourselves on the constitutional provision that, in matters of health protection, it is up to national law to establish the general principles, we would also have to admit that it is up to the regions to define in detail what health is. This is clearly unacceptable, as it would otherwise result in different definitions of health between different regions."

[444] In this context, it is possible to identify an almost uniform approach by the Court in bringing the role of the state legislator in defining the right back to the task assigned to it in determining the fundamental principles of health protection referred to in the third paragraph of Article 117 of the Constitution. On the subject of the relationship between principles and detailed regulations, there is a vast body of case law that follows a path that can be said to be consistent with the desire of the judges of the Court to extend the scope of state intervention whenever it is necessary to ensure uniformity, not only of the right to health, but also of other interests (see, in particular, Constitutional Court ruling no. 331 of 2003). in this sense, the ruling on anti-smoking legislation, in which the Court categorically ruled out any possibility of differentiation, linking protection from passive smoking to the protection of the right to health (ruling no. 361 of 2003, Constitutional Court); in this sense, also the ruling in which the definition of permitted and non-permitted therapies was brought back within the scope of the definition of the fundamental principles of the matter referred to in the third paragraph of Article 117 of the Constitution (ruling no. 361 of 2003, Constitutional Court); and, most recently, in the context of determining mandatory vaccinations (Constitutional Court ruling no. 5 of 2018).

[445] A. Pioggia, *Health and Social Services Law,* op. cit.

levels of service as an exclusive state competence. The matter under discussion falls within the scope of the division of powers, reflecting the typical features of those essential levels that found their first test of regulatory positivization in the field of healthcare[446].

It is precisely through the attribution of exclusive legislative competence with regard to essential levels that the minimum uniformity necessary to ensure that the margins of regional autonomy in this area do not become such as to hinder and prejudice compliance with the principle of equality is guaranteed.

The very category of essential levels has been the subject of numerous debates in constitutional doctrine and jurisprudence, given the definitional ambiguity that characterizes it. Starting from the jurisprudential conclusion that defines the matter under discussion as a "cross-cutting issue"[447], it can be stated, in the words of the Constitutional Court itself, that 'this competence provides the state legislator with a fundamental tool for ensuring the maintenance of adequate uniformity of treatment in terms of the rights of all individuals, even in a system characterized by a significantly increased level of regional and local autonomy'. In relation to the

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[446] As analyzed *below* in Chapter III, § 2.1. Provided for the first time in Legislative Decree No. 502 of 1992, the Essential Levels of Care (as the social and health care version of the more generic Essential Levels of Services found in the Constitution) were defined within the National Health Plan, which, in accordance with the principle of loyal cooperation, was adopted following an agreement between the Government and the Unified Conference, and implemented through the instrument of the Prime Ministerial Decree. The regulation of the Lea was subsequently implemented with the subsequent Legislative Decree No. 229 of 1999, whose regulation stems from the need to introduce mechanisms for verifying and controlling the economic adequacy and actual usefulness of the services included in the LEA. While confirming the possibility of identification through the instrument of the Prime Ministerial Decree, as originally provided for in the 1992 regulation, a control mechanism was subsequently established through the creation of two commissions (the Commission for Monitoring the Implementation of the Prime Ministerial Decree, established by Ministerial Decree of January 19, 2017, of the Minister of Health; and the National Commission for the updating of the LEA, introduced by Law No. 208 of 2015, Article 1, paragraph 556), supported by a Standing Committee for the verification of the provision of Essential Levels of Care (LEA Committee) established by Ministerial Decree of the Minister of Health in 2005; on the regulatory evolution of the Lea, see L. Vandelli, C. Bottari, *Health protection, health planning, and definition of essential and uniform levels of care,* in F. A. Roversi Monaco (ed.), *The National Health Service,* Santarcangelo di Romagna, 2000; E. Balboni, *The concept of 'essential and uniform levels' as a guarantee of social rights,* in *Le istituzioni del federalismo, 6*, 2001; on the updating of the LEA, see in particular M Bergo, The *new essential levels of care. At the crossroads between health protection and budgetary balance,* in *Rivista AIC, 2*, 2017

[447] In constitutional jurisprudence, with regard to competence over the LEPs, there is no mention of a subject in the strict sense, but rather of 'a competence of the state legislator capable of covering all subjects in relation to which the legislator itself must be able to lay down the necessary rules to ensure that everyone, throughout the national territory, can enjoy guaranteed services, as an essential content of those rights', as stated in Sentt. Nos. 282 of 2002, 248 of 2006, 387 of 2007, 50 of 2008, 207 of 2012, 62 of 2020 Constitutional Court.

various attempts to provide an exact definition, it is worth noting the correlation between the concept of essential levels and the minimum core of the right[448] , the definition of which was ultimately contributed to by Constitutional Court ruling no. 192 of 2024[449] .

Based on the valuable guidance provided by the Constitutional Court, it is possible to identify the minimum core of the right as the object whose protection is ensured through the determination of essential levels.

The definition of the relationship of instrumentality between the two concepts, which only appear to coincide, seems to offer useful food for thought in order to identify more clearly the role reserved for the State in the protection of the right to health – both substantive and, as we have seen, organizational.

Faced with a healthcare organization that – necessarily – finds its point of reference in the territories, the central state, in fact, maintains a central role that extends beyond the protection of rights and extends to the healthcare dimension.

In this sense, the role of the Lep takes on full relevance. Defined as a tool through which the state exercises its function as guarantor of equality in the protection of rights, as well as an object through which the protection of the so-called minimum core is implemented; their distinctive cross-cutting nature ensures that they provide an important margin for state intervention in the healthcare sector, the extent of which is case-by-case and depends on specific circumstances in which, in particular, there is a need to balance conflicting requirements that only the national legislature can resolve.

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[448] See R. Bin, *Rights and Misunderstandings: The Issue of Representation,* in Various Authors, *Writings in Honor of Giorgio Berti,* Naples, Esi, 2005.

[449] "The distinction between LEP and the minimum core of the right allows the competence referred to in Article 117, second paragraph, letter m) of the Constitution not to be rendered meaningless; if the two concepts coincided, this provision would assign the state legislator the mere task of making explicit a constraint already deriving from the constitutional provisions on rights. In general, LEPs represent – as mentioned – the result of a balance to be struck," according to the Constitutional Court in judgment no. 192 of 2024 cons. in law 14, which goes on to state that 'the preparatory work for Constitutional Law No. 3 of 2001 shows that the phrase 'minimum levels of guarantee' was replaced by the Chamber with the current formula to ensure uniformity of fundamental rights throughout the country. The aim was to ensure, if possible, a standard of protection higher than the minimum core of the right'.

3. *The role of the state and the financial conditionality of the right to health: the minimum core of the right*

The conceptual reference to the irreducible core of the right has its roots in the Court's case law on the legitimacy of cuts in healthcare spending, which, as highlighted by the judges of the Constitutional Court, are potentially capable of affecting the guarantee of a fundamental right and find their limit of legitimacy precisely in what they themselves have defined as the so-called minimum core of the right; with reference to which, even in the financial context, it is possible to note a recovery of centrality on the part of the State.

Although it has been repeated on several occasions, it seems appropriate to start from the essential premise that the right to health, understood in its dimension as the right to receive healthcare services, is inextricably linked to economic and financial needs, which are expressed in the need to make cuts in public spending, including on healthcare.

On the conditional nature of the right to health, the Court's case law plays an important role in defining the issue and the related limits of the legitimacy of the regulatory provisions on the subject. The Court structures its argument starting from a factual premise, reiterated for the first time in ruling no. 455 of 1990, defined as a 'sort of manifesto decision'[450], which explicitly recognizes the financial conditioning of the right in question.

Through this important ruling, the judges of the Court start from the recognition of the programmatic nature of the provision of Article 32 of the Constitution, from which derives, as a consequence, the close dependence of the effectiveness of this provision on its implementation by the legislator. This implementation, according to the Court, is inevitably linked to and dependent on "the determination of the instruments, timing, and methods of implementation of the relevant protection by the ordinary legislator"[451].

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[450] Thus D. Morana, *Health as a constitutional right,* Giappichelli, 2025

[451] Sentence No. 455 of 1990 Constitutional Court; which goes on to establish that the recognition of the conditional nature of the right "certainly does not imply a downgrading of the primary protection guaranteed by the Constitution to a purely legislative one." what derives from the conditional nature of the right to health is that the relative protection "constitutionally mandatory (...) takes place gradually following a reasonable balance with other interests or assets that enjoy

The effective implementation of the constitutional provision referred to in Article 32 took place through the enactment of the legislation establishing the National Health System - Law No. 833 of 1978 - in which it is possible to note how the ordinary legislator has broadened the boundaries of protection required by the Constitution: compared to the wording of Article 32, which reserves free treatment for the "indigent," the 1978 legislator identified the principles of universality, comprehensiveness, and free treatment as the pillars of the entire system, which was originally entirely supported by state funding.

The 1978 legislative intervention appears to be consistent with the social spirit of the 1948 constitutional order. However, after several decades, the legislature was confronted with accounting requirements relating to the sustainability of the huge state funding of the healthcare sector.

Hence, the systemic interventions of the 1990s aimed—as seen in the previous chapters—at achieving a reduction in healthcare spending by working in multiple directions, such as the corporatization of structures, the modification of spending criteria[452], and through the implementation of the role and responsibility of regional bodies in the National Healthcare System[453].

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equal constitutional protection and with the real and objective possibility of having the necessary resources for its implementation"; it is precisely in this balancing operation that the Court recognizes its role, acknowledging that this discretionary activity "is still subject to the supervision of this Court in the forms and manners appropriate to the use of legislative discretion."

[452] The calculation system, long based on historical regional expenditure, was characterized by the allocation of financial resources to regional authorities not so much on the basis of the actual health needs of the population living there, but rather on the budgetary needs of the regions, identified on the basis of what had been spent in previous financial years. This system "has long prevented or, in any case, rendered ineffective any policy of control or rationalization of expenditure, leading to an increase in costs without guaranteeing any increase in services or their quality," according to A. Pioggia, *Diritto sanitario e dei servizi sociali (Health and Social Services Law),* op. cit.

[453] In particular, Legislative Decree 502 of 1992 introduced the Essential Levels of Care, reserving state financial coverage exclusively for these, leaving those that were subsequently defined as additional or supplementary levels to be financed by the individual regions. This mechanism was made possible by allowing regions to establish forms of co-participation in private expenditure (through so-called tickets on medicines and services) and through the introduction of regional taxes. This process was subsequently developed through Legislative Decree No. 446 of 1997, which introduced the Regional Tax on Productive Activities (IRAP), the revenue from which is entirely allocated to the regions, and was finalized several years later with the introduction of so-called fiscal federalism. Legislative Decree No. 56 of 2000 represents the first real step towards achieving a correspondence between taxes collected at regional level and the use of the resources obtained in the same territory; through this regulatory intervention, the regions were able to finance their own healthcare systems thanks to the revenue obtained from the share paid by professionals practicing private professional activities within the region, from VAT sharing, additional IRPEF (personal income tax) and the entire IRAP tax.

A path towards regional financial accountability that has nevertheless led to an increase in both the gaps between regional healthcare systems and the budget deficits of many regions across the country. The need to rebuild the financing system and ensure uniformity in the protection of rights has led the legislator to establish mechanisms for integrating regional finance[454], through which we have seen a renewed role for the central government in defining a highly centralized system.

The role of the central government in the regional definition of territorial healthcare organization and finance has also grown following the introduction into the Constitution of the principle of balanced budgets, as set out in Article 81 of the Constitution[455], as a result of the economic crisis that culminated in the first decade of the century[456].

This is the context for the state legislation that, starting with the 1992 decree, aimed to introduce measures to contain regional healthcare spending in favor of an increasingly prominent role for the state in coordination, guidance, and control[457].

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[454] Particular reference is made here to the agreement reached at the State-Regions Conference in 2001, following which it was decided to introduce an additional state fund to supplement the resources already allocated. It has been noted that the extensive use of this fund—as a tool for guiding and controlling regional activity—has redefined a highly centralized system, further supported by the gradual introduction of state control and guidance powers in the health sector, which have effectively nullified the regional financing system that had been introduced shortly before. In particular, Legislative Decree 68 of 2011 established the National Standard Healthcare Fund, which, by indicating the overall level of resources available to the National Health Service, aims to supplement the financing of regional systems whose resources derive, on the one hand, from regional self-financing systems and, on the other, from the state equalization fund. on the legislative decree, see F. Politi, *Il decreto legislativo sui costi e fabbisogni standard in sanità: prime valutazioni (*The legislative decree on standard costs and requirements in healthcare: initial assessments)*,* in R. Balduzzi (ed.)*, La sanità italiana alla prova del federalismo fiscale (Italian healthcare put to the test of fiscal federalism*), Il Mulino, 2012.

[455] On constitutional reform law 1 of 2012, see N. Lupo, *Constitution and budget. Article 81 of the Constitution between interpretation, implementation, and circumvention,* Luiss University Press, Rome, 2007; G.M. Salerno, *Constitution, European Union, and global markets,* in *federalismi.it,* 12/2010; G. Goretti, L. Rizzuto, *The constitutionalization of balanced budgets,* in *Forum di quaderni costituzionali,* 2010; A. Pace, *Balanced budgets: something can be done,* in *Rivista AIC,* 3/2011.

[456] On this topic, see L. Califano, *Summary Report to the 28th AIC Conference: on the economic crisis and fundamental rights,* in *Rivista AIC,* 4, 2013.

[457] This refers to the regulation of recovery plans, governed for the first time in Legislative Decree 502 of 1992, as instruments through which 'to achieve a rebalancing of the provision of essential levels of care as set out in the National Health Plan and the Prime Ministerial Decrees on the Lea, as well as to achieve a balanced budget by containing healthcare expenditure within the limits of funding," according to G. Carpani, *Repayment plans between financial emergencies and the fair and appropriate provision of Lea,* in R. Balduzzi (ed.), *Italian healthcare put to the test of fiscal federalism,* Il Mulino, 2012; the author highlights how the minimum content of the Plans can be identified in the necessary presence of three fundamental elements: the assessment of the structural

Given this regulatory activism in the healthcare financing sector, constitutional jurisprudence has had the opportunity, on several occasions, to intervene on the delicate issue of the complex balance between the protection of the right to healthcare services and the balance of public finances.
Taking up the baton from the aforementioned ruling – judgment no. 455 of 1990 – which recognizes the financial conditionality of the right to health, the Court, in the following years, developed a specific approach to the issue of the legitimacy of legislative intervention in the area of financial expenditure containment. In particular, it is essential to mention ruling no. 304 of 1994, in which the Court, reaffirming and recognizing the financial conditionality that characterizes the right to healthcare, generically establishes that this right cannot be totally subordinated to the need to contain public spending; these are in fact limited by the 'essential core of the right' as such connected to the inviolable dignity of the human person[458]. The essential core of the right, identified by the Court as the insurmountable limit to the exercise of legislative balancing, finds its normative translation in the services included in the Essential Levels[459].

Starting from the definition of the right to healthcare services as a financially conditioned right, the Court limits and at the same time justifies the state regulation relating to the containment of healthcare expenditure, on the one hand, identifying in the minimum or irreducible core the limit that must necessarily be subtracted from the balancing with other interests and, on the other hand, the interventions in this sector, despite affecting areas of regional autonomy, are justified precisely to

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causes of the deficit, corrective proposals for structural diseconomies, and possible reformulation of the program. Failure to fulfill the obligations contained in the Plan results in the region concerned being placed under administration pursuant to Article 120 of the Constitution.

[458] Judgment No. 304 of 1994 Constitutional Court, paragraph 5, legal consideration: 'public finance requirements cannot take on such an overwhelming importance as to compromise the essential core of the right to health connected with the inviolable dignity of the human person, otherwise constituting a grossly unreasonable exercise of legislative discretion'.

[459] C. Di Costanzo, *Allocation of resources and protection of health in constitutional jurisprudence,* in *dirittifondamentali.it,* 2, 2021; the author indicates that 'what the legislator establishes as such in the essential levels of services, having as guiding criteria, as established by the Constitutional Court, the constitutional principles of freedom and equality, constitutes an essential part of the right, and is therefore indefectible and inviolable'; on this point, see also B. Pezzini, *Right to health and dimensions of discretion in constitutional jurisprudence,* in Aa. Vv., 2007; which traces the concept of the essential core of the law back to two alternative definitions: on the one hand, 'essentiality is bent in the direction of a minimum level' or 'a level qualitatively characterized as fundamental' to which it is possible to reconnect the idea of 'intrinsic essentiality'.

ensure the effective provision of the services included in the Essential Levels. In support of this thesis, it is possible to find several rulings by the Court aimed at identifying public expenditure intended to finance the provision of services included in the Essential Levels of Care as what has been defined as 'constitutionally necessary expenditure'[460].

It is also possible to identify in the guarantee of Essential Levels the justifying cause, as mentioned above, for the adoption of regulatory measures that are invasive with respect to the division of powers and the principle of loyal cooperation, where the managerial autonomy entrusted to the regions in the health sector prejudices the effective provision of essential services[461] .

Even in the financial context which, as has been said and repeated, characterizes the sphere of the right to health, it is possible to identify the maintenance of the centrality of the central state, which finds the *quantum* and *the an* of its intervention in the essential, irreducible core of the law.

4. *The national state and international organizations in the protection of rights: between transfers of sovereignty and emergency situations*

A reflection on the role of the state in the protection of rights and, in particular, in the protection of the right to health requires that this subject of research be placed in the context of the current legal system, which is characterized by transfers of

[460] It is 'the guarantee of inalienable rights that affects the budget, and not the balance of the budget that conditions their proper provision', according to a passage from judgment no. 275 of 2016 of the Constitutional Court; also in the more recent judgment no. 62 of 2020, the Court refers to 'necessary costs' in relation to the financing of essential levels of care (LEA); referring to the previous ruling no. 169 of 2017 of the Constitutional Court. On the rulings, see A. Apostoli, *Fundamental rights 'seen' up close by the administrative judge. A 'hot' annotation of Constitutional Court ruling no. 275 of 2016,* in *Forum Quaderni costituzionali,* 2017; A. Longo, *A constitutionally oriented concept of the budget: initial reflections on Constitutional Court ruling no. 275 of 2016,* in *Federalismi.it,* 2017; C. Buzzacchi, *The role of 'local hospital health services' in light of the constitutional parameters of budgetary balance and essential levels of care (LEA),* in *Forum Quaderni costituzionali,* 2020; F. Masci, Essential *Levels of Care are not subject to any economic and financial sustainability assessment: a consolidating trend in case law,* in *Forum Quaderni costituzionali,* 2020.

[461] G. Boggero, *The constitutional guarantee of an adequate connection between functions and resources. A "mild" attempt to square the circle between budget, rights, and autonomy,* in *Rivista AIC, 2019;*

national sovereignty to supranational contexts in order to ensure greater and better protection of rights.

The opening up of the legal system to the supranational and international regulatory landscape is also justified by the importance of health, which is inevitably affected by the extreme mobility of goods and people as a consequence of globalization. In fact, the second chapter of this thesis specifically considered how the traditional role of the sovereign state no longer seems adequate, when considered individually, to ensure the protection of what has been defined as global health[462].

The increasingly frequent proliferation of health emergencies and epidemics can be considered an indication of the direct effects of this context, in which the protection of health can no longer be pursued through the isolated action of individual national states.

Given this particular scenario, it seems fair to say that health protection itself is achieved precisely through the transfer of sovereignty that individual states grant to international organizations aimed at ensuring a more adequate level of protection in relation to these needs.

An instrumental view of the limits to national sovereignty, which finds its highest expression in European Union legislation and World Health Organization regulations.

As highlighted in the development of this research, supranational health policies take on significance in terms of domestic law in the form of EU legislation and WHO activities. On the one hand, it is possible to identify the progressive loss of the centrality that the EU reserved for purely economic and financial interests, which corresponds to a renewed awareness of the role played by EU institutions in

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[462] The peculiarity of the aspects that globalization has brought in relation to health protection has led to the birth and development of an autonomous discipline, which takes the name of Global Health, whose original definition derives from the United Institute of Medicine as that set of 'aspects of collective health that transcend national borders, may be influenced by circumstances or changes occurring in other countries, and can be better addressed through cooperative actions and solutions'; Institute of Medicine, *America's vital interest in global health: protecting our people, enhancing our economy, and advancing our international interest,* National Academy Press, Washington, 1997. On the concept of global health, see also F. Francioni, *State sovereignty and the protection of health as a global public good,* in L. Pisaneschi (ed.), *The protection of health in international and European law between global interests and particular interests,* Editoriale Scientifica, Naples, 2017; E. Missoni, G. Pacileo, *Elements of global health. Globalization, health policies, and human health,* FrancoAngeli, 2016

the protection of fundamental rights, including health. on the other hand, it has been noted that the role of the World Health Organization, although supported by concrete contextual findings, is becoming more important in the context of transnational health emergencies, which in fact give rise to a real regulatory power capable of influencing the legislation of Member States[463].

In light of a more careful analysis of this supranational legislation, it has been possible to identify its impact on the domestic legal system both from a purely substantive point of view – given by the various Charters that enshrine the protection of health[464] – and in terms of the importance that these regulatory interventions also have with regard to the organizational-health definition[465].

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[463] On the subject of WHO regulations, see S. Izzo, *Brief considerations on the role of the WHO in combating the Covid-19 pandemic,* in *DPCE online, 2*, 2020; on this point, see R. Virzo, *The proliferation of Institutional Acts of International Organizations – A Proposal for Their Classification,* in R. Virzo, R. Ingravallo (eds.), *Evolutions in the Law of International Organizations,* Leiden, 2015; L. Boisson de Chazournes, *The regulatory power of the World Health Organization: reflection on the scope and nature of the International Health Regulations of 2005,* in *Law of power, power of law: essays presented to Jean Salmon,* Brussels, 2007.

[464] D. Morana, *Initial reflections on the right to health in the Charter of Fundamental Rights of the European Union,* in A. D'Atena, P. Grossi (eds.), *Protection of fundamental rights and multilevel constitutionalism. Between Europe and national states,* Milan, 2004; A. Ciarini, L. Pennacchi, *The Future of Social Rights in Europe: Investments, Actors, and New Policies for a (Different) European Social Model. Introductory Note,* in *Riv. Pol. Soc.,* 2017, 9; S. Cecchini, *Does Europe Aspire to Become a Welfare State?,* in *Rivista AIC, 4*, 2021; A. M. Poggi, *Economic crisis and crisis of social rights in the European Union,* in *Rivista AIC, 1*, 2017

[465] Particular reference is made here to cross-border healthcare (see Chapter II § 2.1); Thus L. Busatta, *Health citizenship in the European Union: the phenomenon of cross-border patient mobility, from free movement to the relational dimension of rights,* in *DPCE online, 3, 2015.* On the regulation of cross-border healthcare contained in the 2011 directive, see also G. M. Salerno, *Cross-border healthcare: issues and prospects,* in *Supreme Courts and Health,* 1, 2022; N. Posteraro, *Care beyond the State: the effectiveness of the right to health in light of Legislative Decree No. 38 of 2014,* in *federalismi.it; L.* Uccello Barretta, *The right to health in the European space: healthcare mobility in light of Directive 2011/24/EU,* in *federalismi.it,* 19, 2014; G. Orlandini, *Economic freedoms and European social citizenship,* in E. Paciotti (ed.), *Fundamental rights in Europe,* Viella, 2011; R. Mastroianni, *Human rights and fundamental economic freedoms in the European Union legal system: a new balance?,* in *European Union law,* 2, 2011. The impact of European legislation on the definition of the healthcare organizational structure can also be seen in the legislation of the National Resilience Plans, on this point L. Chieffi, *A new season for social rights? The boost offered by the Recovery Fund for the relaunch of healthcare welfare,* in *Bio-Law journal Rivista di Biodiritto,* 4, 2021; . F. Salmoni, *Recovery fund, conditionality, and public debt. The great illusion,* Turin, 2021; M. Patrin, *Solidarity and cohesion between continuity and transformation. Cohesion policy as a tool of EU governance,* in *European Union Law,* 3, 2024; F. Costamagna, *Combating poverty and social exclusion as a European Union objective in the relationship between economic, social, and environmental dimensions in the integration process,* in *European Union Law, 2*, 2024; P. Gaggero, *Community programming for recovery and resilience through the prism of solidarity,* in *European Public Law Review,* 1, 2024; A. Conzutti, *Dynamics of the European economic constitution after the pandemic crisis: new advances or old habits?* in *Consultaonline,* 3, 2024; M. Forlivesi, *Next Generation EU: a new frontier of European integration,* in *Lavoro e diritto,* 2, 2023.

Therefore, although the necessity and value of this 'multi-level' regulatory system that characterises health protection cannot be denied, the manner in which the regulatory management of the Covid-19 pandemic emergency has been implemented requires reflection on the pre-eminence given to the role of individual national states[466]. Faced with the submissive attitude adopted by the EU, which was matched by the delay with which the WHO declared a 'transnational health emergency', individual Member States employed totally centralized management methods[467], to the detriment of territorial structures[468] and the recommendations of international organizations, particularly those relating to the management of the so-called ascending phase.

[469]In the fourth chapter, we therefore examined the possible reasons justifying such an attitude of nationalistic supremacy in emergency situations,

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[466] On this topic, see M. Gnes, *The resilience of the Italian healthcare system and the COVID-19 emergency,* in *Global Pandemic Network,* December 2023, vol. 2;

[467] On this point, see M. Gnes, *Pandemic emergency and resilience of the Italian healthcare system,* op. cit.; I. Massa Pinto, *The tremendous lesson of COVID-19 (also) for lawyers,* in *Questione giustizia,* 2020;

[468] The issue of non-compliance with the principle of loyal cooperation, specifically in relation to the measures adopted by the Italian government to manage the pandemic emergency, led to a constitutional dispute that ended with ruling no. 37 of 2021 C. cost., in which the Italian Constitutional Court brought the management of the pandemic emergency back under the scope of international prophylaxis, as a matter falling within the exclusive competence of the State under the division of powers set out in Article 117 of the Constitution. the Italian government's management of the pandemic also gave the Constitutional Court the opportunity to rule on another occasion, regarding the nature of the acts used for management purposes, such as the decrees of the President of the Council of Ministers; on this occasion too, it is possible to note the restoration of the legitimacy of the strategy adopted by the Government, confirmed by ruling no. 198 of 2021; On this subject, see M. Rubechi, *Due 'nuove' rondini ...fanno primavera? Considerazioni su recenti tendenze del regionalismo italiano (Two 'new' swallows... make spring? Considerations on recent trends in Italian regionalism),* in *Federalismi,* 10/2021 M. Francaviglia, *Il sistema dei Dpcm al vaglio della Corte costituzionale (The Dpcm system under scrutiny by the Constitutional Court). First impressions of Constitutional Court ruling no. 198/2021,* in *Diritti Comparati,* 2022; A. Lamberti, *The Constitutional Court and the forced rescue of the DPCMs: observations on Constitutional Court ruling no. 198/2021,* in *Corti supreme e salute,* 1/2022; M. Cavino, *The nature of the Prime Ministerial Decrees adopted in the first phase of the COVID emergency. Reading of Constitutional Court no. 198/2021,* in *Federalismi.it,* no. 25/2021; For contributions on the subject, see M.S. Giannini, *Power of ordinance and necessary acts,* in *Giur. compl. cass. Civ.,* XXVII, 1948; R. Cavallo Perin, *Power of ordinance and principle of legality. Administrative ordinances of necessity and urgency,* Giuffrè Milano, 1990; M. Rubechi, I *decreti del Presidente. Studio sui d.p.c.m., atti normativi del governo e dinamiche decisionali,* Turin, Giappichielli, pp. 131 ff., 2022; M. Rubechi, I *d.P.C.m. della pandemia: considerazioni intorno ad un atto da regolare,* in *federalismi.it,* 27, 2021;

[469] See G. Rolla, *Constitutional aspects of the emergency,* in *Rivista AIC,* 2, 2015; A. Pizzorusso, *Emergency (state of),* in *Encyclopedia of Social Sciences,* Rome, 1993; L. Carlassarre, *States of exception and suspension of constitutional guarantees according to Mortati,* in *The legal thought of Costantino Mortati,* Milan, 1990; G. De Minico, *Should we constitutionalize the emergency?,* in *Observatory on sources,* 2020.

finding them in the 'state of emergency' as *an* extraordinary, unpredictable and temporary factor.
A state of exception that finds its justification in the need to protect the collective dimension of health and which, in turn, refers to a vision and dynamic typical of a narrative of the national state as the guardian of its population.

5. The role of the state: guardian of the 'hard core' of the rights

In light of the considerations made in this concluding section, given a legal, institutional, and economic context in which individual nation states are given less space than the absolute centrality they enjoyed in the past, in the face of transfers of sovereignty "upwards" and demands for autonomy "from below"; in the specific sector of health protection, it seems possible to identify the maintenance of the absolute protagonism of nation states.
As we have attempted to demonstrate in the preceding lines, there are three aspects through which this pre-eminence is most evident. Firstly, this tendency can be seen in the need to ensure uniformity in the protection of rights, a necessity typical of composite forms of state, which is often opposed by demands for autonomy from individual territories, supported by the necessary subsidiarity that permeates the relationship between the center and the territories in our constitutional system[470] .
Although, following the 2001 reform, the constitutional system seems to pay particular attention to the autonomy of individual territories, due to their closer relationship with the population they represent, the primacy of unity finds a way to assert itself through the provision of three areas of state competence: international prophylaxis, coordination of public finance, and determination of essential levels of services. Through these matters, it has been possible to note the affirmation of the expansive power of the state's legislative authority, which finds fertile ground in the specific health sector, where the autonomous demands of the territories seem to recede before the national legislature.

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[470] M. Belletti, *Essential levels of performance and essential content of rights in the jurisprudence of the Constitutional Court,* in L. Califano (ed.), *Constitutional Court and fundamental rights,* Giappichelli publisher, Turin, 2004.

The natural tension between uniformity and autonomy seems to find a synthesis in the provision of essential levels of service—which echoes the previous regulation used in the healthcare sector of essential levels of care—as a "non-subject matter" of a cross-cutting nature, suitable not only for ensuring uniformity in the protection of rights, in the name of the key principle of substantive equality, but also to justify invasive state intervention in the spheres of powers recognized to the regions . [471]
Essential levels do not only seem suitable for representing the implicit limit on regional autonomy; in fact, to the extent that their content coincides with the so-called minimum-essential core of the right, they are removed from the balancing activity carried out by the legislator, which is necessary for the preparation of the service apparatus aimed at realizing the right.

Secondly, the central role recognized to the central state is further manifested in the financing of the healthcare system, or, more precisely, in decisions relating to economic conditionality as a characteristic of the social right to receive healthcare services. The financial situation that permeates issues relating to the right to health affects not only the methods but also the extent of protection. For this reason, established case law has developed an approach aimed at limiting the actions of the legislator, which, by cutting funding for the health sector, often compromised the effectiveness of protection.

While the economic crisis of recent decades has favored *austerity* policies, culminating in the constitutionalization of the principle of a balanced budget, the national healthcare system is still heavily dependent on public funding and therefore closely tied to budgetary policy choices. It is in this context that the Court's jurisprudential orientation comes into play. Following the recognition of the conditional nature of the right to healthcare services with respect to the financial and organizational resources available for its concrete fulfillment, the Court is concerned with removing a portion of this right from the legislator's balancing act, coinciding with the core of the right. This is a form of expression of human dignity,

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[471] F. Gambardella, *Integrated protection of health and the environment for the One Health approach. Organizational platforms and procedural solutions,* Editoriale Scientifica, Naples, 2025; discusses "two-level administrative structure: the state level, which is responsible for policy, the provision of financial resources, and the guarantee of essential levels of care (LEA), (...); the regional level, which is responsible for the executive management of health services."

which cannot be determined a priori, and which finds its effective realization in the Essential Levels of Care, and at the same time the limit of its balance with other interests of public importance – primarily financial ones.

Finally, it has been possible to identify the – only apparently – recessive role of the State in the face of global phenomena, in the face of which the transfer of sovereignty to supranational bodies is identified as a means of protecting the right to health understood in its sense as a global good.

The recent management of the Covid-19 pandemic, although classified as a 'transnational health emergency' and therefore theoretically suitable for management through the regulatory powers of the World Health Organization, has been entirely centralized. In this emergency context, in fact, due to the primary need to protect the health of the population residing in its territory as a constituent element of the same[472] .

In view of these theoretical and practical considerations, it seems possible to affirm that the role of the nation state in protecting the right to health can be said to be anything but recessive, both in relation to territorial divisions and to supranational organizations; these elements seem rather to be identified as instruments through which the state carries out its protective activity. In order to attempt to identify the justification for new state intervention[473] , it seems possible to identify a common thread in the three dimensions outlined here – regional-territorial, financial, supranational – which legitimize a recentralization of powers within the nation state: the protection of the rights, primarily health, of its citizens; a necessary prerequisite for the existence of one of its constituent elements and, therefore, for its very existence.

[472] "The response to the pandemic has been assured by the States, and the role of international and regional organizations has been only ancillary. The World Health Organization (WHO) reaction (based mainly on a warning and advisory role) has been late and often contradictory; the European Union response arrived late and focused mainly on the economic and financial consequences of the pandemic. Regions could only implement national decisions, lacking the necessary legal and political powers and expertise to adopt response plans by themselves. (...) the primary role of the modern State is to protect itself and its citizens," according to M. Gnes, *Wars and fights against pandemics: the re-emerging role of the state as guarantor of last resort,* in *European Review of Public Law,* 34, 2022.

[473] G. Amato, *Bentornato Stato, ma,* Il Mulino, 2022; "We can also say welcome back to the State, whose absence had greatly contributed to the troubles of the early years of the century and whose presence seems indispensable in order to emerge from the troubles in which we increasingly find ourselves today."

BIBLIOGRAPHY

A. Anzon, *L'altra faccia del diritto alla salute,* in *Giurisprudenza costituzionale*, 1979, p. 656 s.;

A. Baldassarre, *Diritti sociali*, in *Enc. Giur.*, XI, Roma, 1989, 29ss.;

A. Barbera C. Fusaro C. Caruso, *Corso di diritto costituzionale,* Bologna, Mulino, 2024;

A. Barbera, *Il peccato originale delle regioni*, in R. Bin, F. Ferrari (a cura di), *Il futuro delle regioni,* Editoriale Scientifica, Napoli, 2023;

A. Castellas, *Autonomia y solidariedad en el sistema de financiacion autonomica,* in *Papeles de Economia Espanola*, 83, 2000;

A. Ciarini, L. Pennacchi, *Il futuro dei diritti sociali in Europa: investimenti, attori e nuove politiche per un (diverso) modello sociale europeo. Nota introduttiva,* in *Riv. Pol. Soc.*, 2017, 9;

A. Conzutti, *Dinamiche della costituzione economica europea dopo la crisi pandemica: nuovo che avanza o vecchio che resta?*, in *Consultaonline*, 3, 2024;

A. D'Aloia, *Diritti e Stato autonomistico,* in E. Bettinelli, F. Rigano (a cura di), *La riforma del Titolo V della Costituzione e la giurisprudenza costituzionale, atti del seminario di Padova svoltosi il 6-7 giugno 2003,* Giappichelli editore, Torino, p. 80 ss.;

A. D'Aloia, *Diritti e Stato autonomistico. Il modello dei Livelli Essenziali delle Prestazioni,* in E. Bettinelli, F. Rigano (a cura di), *La Riforma del Titolo V e la giurisprudenza costituzionale. atti del seminario di Pavia svoltosi il 6-7 giugno 2003*, Giappichelli editore, Torino, 2004;

A. D'Aloia, *Tutela della salute, valutazioni tecnico-scientifiche,limiti all'autonomia regionale. Appunti di giurisprudenza costituzionale*, in L. Violini, (a cura di), *Verso il decentramento delle politiche di* welfare, Giuffrè editore, 2011, p. 19 ss.;

A. D'Aloja, *Diritti e Stato autonomistico. Il modello dei Livelli Essenziali delle Prestazioni,* in Dir. Pubbl., 16, 2004;

A. Davì, *Organizzazione Mondiale della Sanità*, in *Enciclopedia del Diritto,* XXXI, Milano, 1981;

A. De Bernardi, *Pellagra, Stato e scienza medica: la curabilità impossibile*, in F. Peruta (a cura di), *Storia di Italia, Annali 7, Malattia e medicina,* Einaudi, Torino, 1984, pp. 681 ss.;

A. Di Martino, *La doppia dimensione dei diritti fondamentali*, in *Rivista del Gruppo di Pisa,* 2/2016;

A. Di Martino, *La doppia dimensione dei diritti fondamentali*, in *Rivista del Gruppo di Pisa,* 1/2016; A. Celotto, *Diritti (diritto costituzionale)*, in *Dig. Disc. Pubb.*, UTET, 2017, 278 ss.;

A. Di Rienzo, *L'esclusione assoluta del rimborso alle spese di ricovero all'estero è contraria al diritto comunitario,* in *Dir. Pubb. Comp.,* 2, 2007;

A. Dirri, *La leale collaborazione nell'assestamento del PNRR: un regionalismo "esecutivo" per il superamento dei divari territoriali,* in *Rivista AIC,* 1, 2024;

A. Diurni, *Italia e Spagna: sistemi sanitari a confronto,* in *Diritto e Salute*, 2017;

A. Gelblat, L. Marguet, *L'etat d'urgence sanitaire: la doctrine dans tous ses etats?,* in La *Revue des droits de l'homme*, 2020;

A. Iannuzzi, *Leggi science driven e Covid-19. Il rapporto tra politica e scienza nello stato di emergenza sanitaria*, in *Biolaw Journal,* 2020, n. 1;

A. Lamberti, *La Corte costituzionale e il salvataggio forzato dei DPCM: osservazioni a margine di Corte cost., sent. n. 198/2021,* in *Corti supreme e salute,* 1/2022;

A. Mangia, *Tutela della salute e valutazioni tecniche: un limite al regionalismo? Discrezionalità legislativa e valutazioni tecniche*, in L. Violini, (a cura di), *Verso il decentramento delle politiche di* welfare, Giuffrè editore, 2011, p. 51 ss.;

A. Mattioni, *Le quattro riforme della sanità. Una lettura sinottica di snodi istituzionali fondamentali*, in R. Balduzzi (a cura di), *Trent'anni di Servizio sanitario nazionale*. *Un confronto interdisciplinare*, Mulino, Bologna, 2009;

A. Monica, *Tutela della salute e "amministrazione di emergenza" europea,* in *Ius et Salus* Rivista di Diritto Sanitario e Farmaceutico, 2020;

A. Morrone, *Il caso e la sua legge. Note sulla vicenda Cappato/Dj Fabo*, in *Famiglia e Diritto*, 3/2020;

A. Morrone, *La Corte costituzionale riscrive il Titolo V,* in *Quaderni Costituzionali*, 2003;

A. Nania, *La sospensiva cautelare: dal conflitto di attribuzioni tra stato e regioni al giudizio sulle leggi,* in *federalismi*, 2002;

A. Napolitano, *La dimensione multilivello del diritto alla salute. Esigenze di tutela e vincoli di sistema,* Editoriale scientifica, 2025;

A. Pace, *Problematica delle libertà costituzionali. Parte generale,* Padova, CEDAM, 1980;

A. Papa, *La tutela multilivello della salute nello spazio europeo: opportunità o illusione*, in www.federalismi.it, 4, 2018;

A. Patroni Griffi, *Scienza e diritto ai tempi dell'emergenza da Covid-19, qualche annotazione*, in G. De Minico, M. Villone (a cura di), *Stato di diritto – emergenza – tecnologia*, in *consulta-online,* 2020;

A. Pioggia, *Il diritto alla salute alla prova della differenziazione: autonomie, organizzazione, dis-eguaglianza,* in *Istituzioni del federalismo*, 1, 2020;

A. Pioggia, *Diritto sanitario e dei servizi sociali*, Giappichelli, Torino, 2024;

A. Pitino, *Autonomie e salute,* in A. Morelli, L. Trucco, *Il valore delle autonomie nell'epoca repubblicana*, Giappichelli, Torino, 2015;

A. Ridolfi, *Il diritto a morire è un diritto costituzionalmente tutelato? (Considerazioni a partire dai casi Cappato-Antoniani e Trentini)*, in *Costituzionalismo.it*, 1/2021;

A. Ruggeri, *Effetti diretti delle norme eurounitarie e costituzione,* in *Rivista AIC,* n. 2, 2015;

A. Spadaro, *Integrazione europea e costituzionalismo globale,* in *DPCEonline,* n. 2/2021;

A. Ruggeri, *Fine-vita (problemi e prospettive)*, in *Consulta online*, 1/2023;

A. Ruggeri, *L'autonomia territoriale oggi, dal punto di vista della teoria della Costituzione*, in *Diritti Regionali*, 1/2024;

A. Ruggeri, *La disciplina del suicidio assistito è "legge" (o meglio, "sentenza-legge"), frutto di libera invenzione della Consulta A margine di Corte cost. n. 242 del 2019*, in *Quaderni di diritto e politica ecclesiastica*, 3/2019;

A. Saporito, *Il Piano Nazionale di Ripresa e Resilienza e il diritto alla salute, una nuova evoluzione?,* in *Amministrativ@mente,* 1/2024;

A. Simoncini – C. Di Costanzo, *Il contributo della Corte costituzionale allo sviluppo del biodiritto*, in *BioLaw Journal – Rivista di Biodiritto*, 2/2019;

A. Simoncini, E. Longo, *Articolo 32*, in R. Bifulco, A. Celotto, M. Olivetti (a cura di), *Commentario alla Costituzione,* vol. I, UTET Giuridica, Torino, 2006, 657 ss;

A. Spagnolo, *Contromisure dell'organizzazione mondiale della sanità come conseguenza di violazione dei regolamenti sanitari internazionali in contesti*

epidemici, in L. Pisaneschi (a cura di), *La tutela della salute nel diritto internazionale ed europeo tra interessi globali e interessi particolari*, Editoriale Scientifica, 2017;

A.M. Poggi, *Crisi economica e crisi dei diritti sociali nell'Unione europea,* in *Rivista AIC,* 1, 2017;

Astrid, *La riforma del Titolo V della Costituzione e i problemi della sua attuazione,* 2002;

B. Caravita, A. Morrone, *Ambiente e Costituzione,* in B. Caravita, L. Cassetti, A. Morrone (a cura di), *Diritto dell'ambiente*, Bologna, 2016, pp. 17 ss.;

B. Caravita, *La disciplina costituzionale della salute,* in *Diritto e società*, 1984;

B. Caravita, *La sentenza della Corte sulla Valle d'Aosta: come un bisturi nel burro delle competenze (legislative) regionali,* in Federalismi, 2020;

B. Cerchi, *Stato d'assedio e sospensione delle libertà nei lavori dell'Assemblea costituente,* in *Rivista trimestrale di diritto pubblico,* 1981, p. 1121 ss.;
B. Gobbi, *Piano pandemico dell'OMS, ecco perché l'Italia si è astenuta (insieme ad altri dieci Paesi)*, www.ilsole24ore.it, maggio, 2025;

B. Pezzini, *Il diritto alla salute: profili costituzionali*, in *Diritto e società*, 1983;

B. Pezzini, *Il riordino del 1992 (un sistema sanitario universale, nonostante il riordino del 1992)*, in *Corti Supreme e Salute*, 3, 2018;

B. Pezzini, *Principi costituzionali e politica nella sanità: il contributo della giurisprudenza costituzionale nella definizione del diritto sociale alla salute*, in C.E Gallo, B. Pezzini (a cura di), *Profili attuali del diritto alla salute*, Milano, Giuffrè, 1998;

C. Bottari, *Tutela della Salute e organizzazione sanitaria*, Giappichelli, Torino, 2009;

C. Acocella, *Ancora su diritto e tecnica. Le valutazioni tecnico-scientifiche come premessa delle decisioni politico-amministrative per fronteggiare l'emergenza pandemica da Covid-19,* in *PA Persona e Amministrazione,* 2020;

C. Bottari, *Il diritto alla tutela della salute*, in R. Nania, P. Ridola (a cura di), *I diritti costituzionali*, Vol. II, Giappichelli, Torino, 2002.;

C. Bottari, *Il diritto alla tutela della salute,* in R. Nania, P. Ridola (a cura di), *I diritti costituzionali*, vol. I, Giappichielli, Torino, 2006, 764 ss.;

C. Chimenti, *Noi e gli altri*, vol. II, Parte II, Giapichelli Editore, Torino;

C. Colapietro, *I diritti sociali oltre lo Stato. il caso dell'assistenza sanitaria transfrontaliera,* in *costituzionalismo.it*, 2, 2018;

C. Colapietro, *La forma di Stato e di governo italiana alla prova del Piano nazionale di ripresa e resilienza*, in *Rivista AIC*, 3, 2022;

C. Fasone, *Tutela della salute (art. 117. 3),* in R. Bifulco, A. Celotto (a cura di), *Le materie dell'art. 117 nella giurisprudenza costituzionale dopo il 2001,* Napoli, 2005;

C. Guerrero Picò, *Spagna,* in P. Passaglia (a cura di), *Poteri emergenziali e deroghe al principio di legalità*, 2011;

C. Mortati, *Articolo 1*, in G. Branca, *Commentario alla Costituzione*, Bologna-Roma, 1975;

C. Mortati, *Ispirazione democratica della Costituzione*, in *Scritti*, vol. II, Milano, 1972, 280 ss.;

C. Mortati, *La tutela della salute nella Costituzione italiana*, in *Scritti*, vol. III, Giuffrè, Milano, 1972, p. 433 ss.;

C. Pinelli, *I Livelli essenziali delle prestazioni, Federalismo fiscale alla prova dei decreti delegati. 57° Convegno di studi amministrativi*, Varenna, 22-24 settembre 2011;

C. Sartoretti, *La risposta francese all'emergenza sanitaria da Covid-19: Stato di diritto e Costituzione alla prova della pandemia,* in *DPCE online*, 2/2020, p. 1637 ss.;

C. Schmitt, *Verfassungslehre*, Berlino, 1954, 169 ss.;

C. Smith, *La dittatura*, 1921;

D. Fidler, *SARS, Governance and the Globalization of the Disease,* Palagrave MacMillan, New York, 2004, p. 26 ss.;

D. Morana, *La salute come diritto costituzionale*, Giappichelli, Torino, 2025;

D. Morana, *La tutela della salute fra competenze statali e regionali: indirizzi della giurisprudenza costituzionale e nuovi sviluppi normativi*, in Osservatorio AIC, 1, 2018;

D. Morana, *Le norme statali di dettaglio in materia sanitaria tra vecchio e nuovo Titolo V: spunti dalla giurisprudenza costituzionale*, in L. Violini, (a cura di), *Verso il decentramento delle politiche di* welfare, Giuffrè editore, 2011, p. 135 ss.;

D. Morana, *Prime riflessioni sul diritto alla salute nella Carta dei diritti fondamentali dell'Unione Europea,* in A. D'Atena, P. Grossi (a cura di), *Tutela dei diritti fondamentali e costituzionalismo multilivello. Tra Europa e Stati nazionali,* Milano, 2004;

D. Morana, *Principio di solidarietà, diritto alla salute e obblighi vaccinali*, in *Diritti comparati*, 2024;

D. Morana, *Tutela della salute*, in G. Guzzetta, F.S. Marini, D. Morana (a cura di), *Materie di competenza regionale. Commentario,* Napoli, 2015;

D. P. Fidler, *From International sanitary conventions to Global Health Security: the new International Health Regulations,* in *Chinese Journal of International Law*, 2005, Oxford University Press;

D. Paris, *Il ruolo delle regioni nell'organizzazione dei servizi sanitari e sociali a sei anni dalla Riforma del Titolo V: ripartizione delle competenze e principio di sussidiarietà,* in *Le Regioni*, 6, 2007;

D.U. Galetta, *Il principio di proporzionalità fra diritto nazionale e diritto europeo (e con uno sguardo anche al di là dei confini dell'Unione Europea),* in *Rivista italiana di diritto pubblico comunitario,* 2019 n. 6;

E. Aja, *Estado autonomico y reforma federal*, Madrid, 2014;

E. Balboni, *il concetto di" livelli essenziali ed uniformi" come garanzia in materia di diritti sociali*, in *le istituzioni del federalismo,* 6, 2001;

E. Buglione, G. France, *Skewed fiscal federalism in Italy: implications for public expenditure control*, in *Public budgeting & finance*, 3, 1983;

E. Catelani, *Il P.N.R.R. e l'ordinamento costituzionale: un'introduzione,* in *Rivista AIC,* 3, 2022.

E. Catelani, *Nuove richieste di autonomia differenziata ex art. 116, comma 3, Cost: profili procedimentali di dubbia legittimità e possibile violazione dei diritti*, in *www.osservatoriosullefonti.it,* 1, 2018;

E. Cavasino, *Perché costruire il diritto alla salute come "diritto a prestazione" rende le forme normative dell'uguaglianza dipendenti dal limite economico-finanziario e ridimensiona l'effetto garantistico del "contenuto minimo essenziale"*, in *Gruppo di Pisa;*

E. Cavasino, *Perché costruire il diritto alla salute come "diritto a prestazione" rende le forme normative dell'eguaglianza dipendenti dal limite economico-finanziario e ridimensione l'effetto garantistico del "contenuto minimo essenziale"*, in *Gruppo di Pisa*, 3, 2012;

E. Cheli, *La forma dello Stato regionale in una storica sentenza della Corte costituzionale*, in *astridonline.it*, 18/2024;

E. Cirone, *Salute pubblica e diritto dell'Unione,* in *Osservatorio sulle fonti* 2/2021, p. 655;

E. Di Salvatore, *Brevi osservazioni sulla revisione degli articoli 9 e 41 della Costituzione*, in *Costituzionalismo.it*, fasc. n. 1/2022;

E. Ferrari, *I servizi sociali*, vol. I, Milano, 1986;

E. Forsthoff, *Stato di diritto in trasformazione*, Milano, 1973;

E. G. Reguera, *Esperienze e prospettive del regionalismo in Spagna,* 2006;

E. Greppi, *OMS (Organizzazione Mondiale della Sanità), in Novissimo Digesto Italiano*, Torino, 1987;

E. Griglio, *Unità e decentramento nella tutela del diritto alla salute in Spagna*, in R. Balduzzi (a cura di), *Sistemi costituzionali, diritto alla salute e organizzazione sanitaria: Spunti materiali per l'analisi comparata*, Il Mulino, Bologna, ,2009;

E. Lamarque, *Sospensione cautelare di legge regionale da parte della Corte costituzionale (Nota a Corte cost. 14 gennaio 2021 n. 4)*, in *Giustizia Insieme;*

E. Longo, *il diritto ai migliori trattamenti sanitari nella giurisprudenza di Lussemburgo,* in *Quaderni costituzionali*, 2007;

E. Menichetti, *La tutela della salute tra competenze "divise" e interessi "concordati". Riflessioni sul destino del servizio sanitario nazionale nel nuovo Titolo V della Costituzione*, in R. Balduzzi (a cura di), *La sanità italiana tra livelli essenziali di assistenza, tutela della salute e progetto di devolution*, Milano, 2004;

E. Missoni, G. Pacileo, *Elementi di salute globale. Globalizzazione, politiche sanitarie e salute umana*, FrancoAngeli, 2016;

E. Pesaresi, *La "determinazione dei livelli essenziali delle prestazioni" e la materia della" tutela della salute": la proiezione indivisibile di un concetto unitario di cittadinanza nell'era del decentramento istituzionale,* in *Giurisprudenza costituzionale*, 2, 2002;

E. Pesaresi, *La determinazione dei livelli essenziali delle prestazioni e la materia "tutela della salute": la proiezione indivisibile di un concetto unitario di cittadinanza nell'era del decentramento istituzionale,* in Giurisprudenza costituzionale,, 2, 2006;

E. Rossi, *Le Case della comunità del PNRR: alcune considerazioni su un'innovazione che merita di essere valorizzata*, in *Corti Supreme e Salute*, 2, 2021;

F. Angelini, M. Benvenuti, *Il riparto delle funzioni (Blegio)*, in R. Bifulco (a cura di)*, Ordinamenti federali comparati*, II, 2021;

F. Bestagno, *La tutela della salute tra competenze dell'Unione europea e degli Stati membri,* in *Studi sull'integrazione europea,* 2/2017, p. 317 ss.;

F. Cammeo, *Sanità pubblica*. *Principi generali, fonti ed organi dell'amministrazione sanitaria*, in F. Cammeo, C. Vitta, *Sanità pubblica*, in V. E. Orlando (a cura di), *Trattato di Diritto Amministrativo Italiano*, vol. IV, II parte, Milano, Società Editrice Libraia, 1905, 213 ss;

F. Cintioli, *Sul regime del* lockdown *in Italia. Note sul decreto legge n. 19 del 25 marzo 2020,* in *Federalismi.it, Osservatorio emergenza Covid*, 2020;

F. Costamagna, *Il contrasto alla povertà e alla esclusione sociale quale obiettivo dell'Unione europea nel rapporto tra dimensione economica, sociale ed ambientale nel processo di integrazione*, in *Il Diritto dell'Unione europea,* 2, 2024;

F. Della Peruta, *Sanità pubblica e legislazione sanitaria dall'Unità a Crispi*, in *Studi Storici*, 4/1980, pp. 713 ss;

F. Francioni, *Sovranità statale e tutela della salute come bene pubblico globale,* in L. Pisaneschi (a cura di), *La tutela della salute nel diritto internazionale ed europeo tra interessi globali e interessi particolari,* Editoriale Scientifica, Napoli, 2017;

F.G. Cuttaia, *Il recupero della centralità del diritto alla salute. Prospettive di riforma del Servizio sanitario nazionale*, Giappichelli, Torino, 2022;

F. Gallaranti, *Le libertà fondamentali alla prova del coronavirus. La gestione dell'emergenza sanitaria in Spagna e in Francia*, in L. Cuocolo (a cura di), *I diritti costituzionale di fronte all'emergenza Covid-19. Una prospettiva comparata,* in *Federalismi.it*, osservatorio emergenza Covid-19, 2020;

F. Gallarati, *Gli obblighi costituzionali di protezione: studio comparato sul lato "dimenticato" dei diritti fondamentali*, in *Rivista AIC,* 2/2024;

F. Gambardella, *La tutela integrata della salute e dell'ambiente per l'approccio* One health*. Piattaforme organizzative e soluzioni procedimentali*, Editoriale Scientifica, Napoli, 2025;

F. Lanchester, *Le Costituzioni degli altri*, Giuffrè editore, Milano, 2005;

F. Losurdo, *Stabilità e crescita da Maastricht al Fiscal compact,* in *Cultura giuridica e diritto vivente*, 2015;

F. M Lazzaro, *La partecipazione dei Comuni all'esercizio di funzioni sanitarie e sociali*, in R. Balduzzi; G. Di Gaspare (a cura di), *Sanità e assistenza dopo la riforma del Titolo V*, Giuffrè, 2002;

F. Masci, *La dignità umana quale "bilancia" del conflitto tra diritto alla salute della persona detenuta e sicurezza sociale,* in DPCE online, 2, 2024;
F. Minni A. Morrone, *Il diritto alla salute nella giurisprudenza della Corte costituzionale italiana,* in *Rivista AIC,* 2013;

F. Polacchini, *I riflessi del Pnrr sulla forma di governo e sui processi di indirizzo politico*, in *Forum di Quaderni Costituzionali*, 4, 2022, 234;

F. Politi, *Libertà costituzionali e diritti fondamentali*, Torino, Giappichelli, 2021;

F. Rolando, *La tutela della salute nel diritto delll'Unione europea e la risposta dell'UE all'emergenza Covid-19,* in *L'emergenza sanitaria Covid-19 e il diritto dell'Unione europea. La crisi, la cura, le prospettive,* *www.*Eurojus.it, special issue ;

F. Salmoni, *Recovery fund, condizionalità e debito pubblico. la grande illusione*, Torino, 2021; M. Patrin, *Solidarietà e coesione tra continuità e trasformazione. La politica di coesione come strumento di governance dell'Unione*, in *Il diritto dell'Unione europea*, 3, 2024;

F. Taroni, *La sanità in Italia dall'Unità al Servizio Sanitario nazionale,* in *Manuale critico di Sanità pubblica*, Maggioli, Rimini, 2011;

F. Taroni, *Prima e dopo quel difficile dicembre 1978*, in *Corti Supreme e Salute*, 3, 2018;

F. Taroni, *Salute, sanità e regioni in un Servizio sanitario nazionale*, in M. Salvati, L. Sciolla, *L'Italia e le sue regioni. L'età repubblicana,* vol. I, Roma, Istituto dell'Enciclopedia Treccani, p. 411 ss.;

F. Taroni, *Sanità e regioni in un Servizio sanitario nazionale,* in M. Salvati, L. Sciolla (a cura di), *L'Italia e le sue regioni,* Treccani, 2015;

F. Taroni, *Sanità e regioni in un servizio sanitario nazionale,* in M. Salvati, L. Sciolla, *L'Italia e le sue regioni. L'età repubblicana*, vol. I, Istituto dell'enciclopedia Treccani, 411;

F. Urso, *Ambiente, ecosistema e biodiversità. Alcune riflessioni a partire da un progetto di revisione costituzionale*, in *Annali – Università Suor Orsola Benincasa*, Vol. I, 2021, pp. 81 ss;

F.G. Cuttaia, *Il condizionamento finanziario del diritto sociale alla salute: fondamento e prospettive evolutive, astrid-online,* 9,2020;

F.J. Sanz Larruga, *Las competencias del Estado, Comunitades Autonomas y Corporaciones locales en materia sanitaria*, in Goméz-Diàa Castroverde- Sanz Larruga (dir. Da), *Lecciones de Derecho Sanitario*, Universitade da Coruna, La Coruna, 1999;

F.M. Lazzaro, *La partecipazione dei comuni nell'esercizio delle funzioni sanitarie e sociali*, in R. Balduzzi, G. Di Gaspare (a cura di), *Sanità e assistenza nel nuovo Titolo V*, Milano, 2002;

F.M.F. Melacrinis, *Quando la conoscenza guida l'azione politica: la legge Crispi-Pagliani del 1888*, in *Studi* Politici, 2/2024;

G. Amato, *Forme di Stato e Forme di governo,* Il Mulino, Bologna, 2006; B. Caravita (a cura di), *Le regioni in europa, esperienze costituzionali a confronto*, Giampiero Casagrande Editore, Roma, 2002;

G. Amato, *Bentornato Stato, ma,* il Mulino, 2022;

G. Baldini, *Riflessioni di Biodiritto. Profili evolutivi e nuove questioni,* Milano, 2019;

G. Baldini, *Riflessioni di Biodiritto. Profili evolutivi e nuove questioni*, CEDAM, 2019;

G. Battistella, *Il diritto all'assistenza medica a morire tra l'intervento "costituzionalmente obbligato" del Giudice delle leggi e la discrezionalità del Parlamento. Spunti di riflessione sul seguito legislativo*, in *Osservatorio AIC*, 1/2020;

G. Bognetti, *Europa in crisi: due studi su alcuni aspetti della fine della II Repubblica francese e la Repubblica di Weimar,* Milano, 1991;

G. Burdeau, *Traité de science politique*, Parigi, 1956, vol IV, 361 ss.;

G. Caporali, *La legge quadro sull'autonomia differenziata: un'analisi delle criticità e delle prospettive*, in *Italian papers on federalism*, 3/2024;

G. Carpani, *Commento all'art. 2*, in F.A. Roversi Monaco (a cura di), *Il nuovo servizio sanitario nazionale*, Rimini, 2000;

G. Carpani, D. Morana, *Le competenze legislative in materia di "tutela della salute"*, in *Manuale di diritto sanitario*, Bologna, 2013;

G. Comazzetto, *I livelli essenziali delle prestazioni tra processi di differenziazione ed esigenze di uguaglianza*, Jovene editore, 2024;

G. De Minico, *Costituzionalizziamo l'emergenza?*, in *Osservatorio sulle fonti,* 2020;

G. De Vergottini, *Diritto Costituzionale Comparato,* Cedam, Padova;

G. De Vergottini, *Diritto costituzionale comparato,* Padova, 2019;

G. Di cosimo, *Materie (riparto di competenze),* in *Digesto delle Discipline Pubblicistiche, UTET*;

G. Falcon, *Viaggio al centro del PNRR*, in *Le Regioni*, 4, 2021;

G. Guzzetta, *Potenzialità, rischi e aspettative dell'autonomia differenziata*, in *Nuove Autonomie*, 1/2024;

G. L. Burci, *Tutela della salute ed evoluzione della sicurezza collettiva*, in L. Pisaneschi (a cura di), *La tutela della salute nel diritto internazionale ed europeo tra interessi globali e interessi particolari*, Editoriale scientifica, 2017;

G. Leibholz, *Der Strukturwandel der modernen Demokratie*, in *Strukturprobleme dei modernen Demokrtie,* Karlusruhe, 1958, 88;

G. M. Salerno, *L'assistenza sanitaria transfrontaliera: problematiche e prospettive*, in *Corti Supreme e Salute*, 1, 2022;

G. M. Salerno, *Leale collaborazione*, in M. Cartabia e M. Ruotolo (a cura di), *Enciclopedia del diritto. I Tematici, Potere e Costituzione*, Milano, Giuffrè, 2023;

G. Milani, *L'emergenza sanitaria nel diritto pubblico comparato: la risposta del Belgio al Covid-19*, in *DPCEonline*, 2/2020, p. 1167 ss;

G. Mor, *Il nuovo assetto organizzativo del Servizio sanitario nazionale*, in *Sanità pubblica*, 6, 1997;

G. Oestreich, *Storia dei diritti umani e delle libertà fondamentali (1978)*, G. Gozzi (a cura di), Roma-Bari, Laterza, 2001;

G. Ognibeni, *Legislazione e organizzazione sanitaria nella seconda metà dell'Ottocento*, in M.L. Betri, A. Gigli Marchetti (a cura di), *Salute e classi lavoratrici in Italia dall'Unità al fascismo,* Angeli, Milano, 1982, 583 ss.;

G. Orlandini, *Libertà economiche e cittadinanza sociale europea,* in E. Paciotti (a cura di), *I diritti fondamentali in Europa*, Viella, 2011;

G. Pizzorusso, *Emergenza stato di,* in *Enciclopedia Treccani*, 1993;

G. Ragone, *One Health e costituzione italiana, tra spinte ecocentriche e nuove prospettive di tutela della salute umana, ambientale e animale*, in *Corti Supreme e Salute*, 3, 2022;

G. Ragone, *One Health e Costituzione italiana, tra spinte ecocentriche e nuove prospettive sulla tutela della salute umana, ambientale e animale,* in Corti Supreme e Salute 3/2022;

G. Razzano, *PNRR: le cure primarie, fra opportunità di una "transizione formativa" e unità di indirizzo politico e* amministrativo, in *Corti Supreme e* Salute, 2, 2022;

G. Rolla, *Profili costituzionali dell'emergenza,* in *Rivista AIC*, n. 2/2015;

G. Vicarelli, *Alle radici della politica sanitaria in Italia, Società e salute da Crispi al fascismo*, Il Mulino, Bologna, 1997;

G.L.Burci, *WHO (World Health Organization),* in S. Cassese (a cura di), *Dizionario di diritto pubblico*, IV, Milano, 2006;

G.M. Salerno, *Autonomia differenziata: problema o prospettiva costituzionale?*, in *federalismi.it*, 19/2023;

H. P. Schneider, *Caratteri e funzione dei diritti fondamentali nello Stato costituzionale*, in *Diritto e Società*, 2/1979, 220 ss.;

I. A. Nicotra, *L'ingresso dell'ambiente in costituzione, un segnale importante dopo il* Covid, in *federalismi.*it, 2021;
I. Kaul, I. Grunberg, M. Stern, *Global public goods: international cooperation in the 21st century*, Oxford Academic, 1999;

J. Jeller- Noller, *The solidarity Clause of the Lisbon Treaty,* in *Think Global – Act European: The Contribution of 16 European Think Tanks to the Polish, Danish and Cypriot Trio Presidency of the European Union,* 2011, p. 328 ss.;

J. Jiménez Campo, *Que es lo basico? Legislacion compartida en el Estado autonomico*, in *Rivista Espanola de Derecho Constitucional*, 27, 1987;

J. Locke, *Trattato sul Governo*, 1690;

J. Ruiperez Alamillo, *Sobre la naturaleza del Estado de las Autonomias,* in *Revista de Estudios Politicos*, 81/1993;

J.M. Fernandez, *El nuevo sistema de financiacion autonomica,* in *Revista de Contabilidad y Tributacion*, Centro de Estudios Financieros, 228, 2000;

L. Boisson de Chazournes, *Le pouvoir reglementaire de l'Organisation Mondiale de la Santè: réflexion sur la portée et la nature du Règlement Sanitaire International de 2005,* in *Droit du pouvoir, pouvoir du droit: mélanges offerts à Jean Salmon,* Bruxelles, 2007;

L. Antonini, *Tecniche decisorie e bilanciamento tra diritti e finanze*, in F. Pammolli, C. Tucciarelli (a cura di), *Il costo dei diritti*, Bologna, 2021;

L. Busatta, *La cittadinanza della salute nell'Unione europea: il fenomeno della mobilità transfrontaliera dei pazienti, dalla libera circolazione alla dimensione relazionale dei diritti,* in *DPCE online, 3, 2015;*

L. Califano (a cura di), *Corte costituzionale e diritti fondamentali*, Giappichelli editore, Torino, 2004;

L. Califano, *Fascicolo sanitario elettronico (Fse) e dossier sanitario*, in *Sanità pubblica e privata*, 3, 2021;

L. Califano, *I nodi irrisolti del regionalismo italiano*, in *Cultura giuridica e diritto vivente*, 10, 2022;

L. Califano, *Relazione di sintesi al XXVIII Convegno AIC: in tema di crisi economica e diritti fondamentali*, in *Rivista AIC*, 4, 2013;

L. Califano, F. Fabrizzi, M. Rubechi, *Guida ragionata alla Costituzione italian*a, Maggioli editore, Rimini, 2024;

L. Castelli, *I nodi pendenti dell'attuazione dell'art. 116 terzo comma della Costituzione*, in *Diritti regionali*, 3/2023;

L. Chieffi, *Equità nella salute e nei servizi sanitari tra politiche europee e interventi statali*, in *Corti Supreme e Salute*, 1, 2022;

L. Chieffi, *La tutela del diritto alla salute tra prospettive di regionalismo differenziato e persistenti divari territoriali,* in *Nomos le attualità del diritto*, 1, 2020;

L. Chieffi, *Una nuova stagione per i diritti sociali? La spinta offerta dal Recovery fund per il rilancio dei welfare sanitari,* in *Bio-Law journal Rivista di Biodiritto*, 4, 2021;

L. Cuocolo, A. Candido, *L'incerta evoluzione del regionalismo sanitario in Italia,* in *Quaderni Costituzionali,* 2013;

L. Cuocolo, *I diritti costituzionali di fronte all'emergenza Covid-19: la reazione italiana,* in *I diritti costituzionale di fronte alla emergenza sanitaria. Una prospettiva comparata*, *Federalismi.it*, Osservatorio emergenza Covid;

L. Cuocolo, *La tutela della salute tra neoregionalismo e federalismo. Profili di diritto interno e comparato*, Giuffrè- Luiss University Press, 2005;

L. Durst, *Fragilità e frammentazione del diritto alla salute in tempo di pandemia*, in C. Caporale, C. Collicelli, L. Durst (a cura di), *Dopo la pandemia. Appunti per una nuova sanità*, in *Etica della ricerca, bioetica, biodiritto e biopolitica*, II, 2022;

L. J. Quesada, *Articulo 43*, in *Comentario a la Constitucion Espanola, 40 aniversario 1978-2018,* Tirant lo blanch, Valencia, 2018;

L. Melica, *Il sistema sanitario spagnolo e la tutela della salute degli immigrati: spunti di riflessione*, in *Rivista AIC*, 4, 2017;

L. Trucco, *Diritti sociali e livelli essenziali delle prestazioni tra politiche legislative e Corte costituzionale,* in E. Cavasino, G. Scala, G.Verde (a cura di), *Diritti sociali dal riconoscimento alle garanzie: il ruolo della giurisprudenza*, Atti del Convegno annuale del Gruppo di Pisa, svoltosi 8-9 giugno 2012-Trapani, Editoriale Scientifica, Napoli, 2013;

L. Uccello Barretta, *Il diritto alla salute nello spazio europeo: la mobilità sanitaria alla luce della direttiva 2011/24/UE,* in *federalismi.it*, 19, 2014;

L. Vandelli, C. Bottari, *Tutela della salute, programmazione sanitaria e definizione dei livelli essenziali e uniformi di assistenza,* in F. A. Roversi Monaco (a cura di), *Il servizio sanitario nazionale*, Santarcangelo di Romagna, 2000;

L. Violini, *Livelli essenziali e regionalismo differenziato: riflettendo sui nessi tra l'art. 117, II comma, lett. m) e l'art. 116, III comma della Costituzione alla luce dei lavori del CLEP*, in *federalismi.it*, 2024;

M .Trimarchi, *Politiche di bilancio e vincoli europei*, in *Il diritto dell'economia,* 3, 2023; A. Saitta, *"Fiscal compact" tra Costituzione, trattati e politica*, in *Rivista AIC*, 4, 2017;

M Atripaldi, *Diritto alla salute e livelli essenziali di assistenza*, *federalismi.it*, 2017

M Bergo, *I nuovi livelli essenziali di assistenza. Al crocevia tra tutela della salute e l'equilibrio di bilancio*, in *Rivista AIC,* 2, 2017;

M. A. Sandulli, *Sanità, misure abilitanti generali sulla semplificazione e giustizia nel PNRR*, in *federalismi.it*, 2021;

M. Bignami, *Chiacchiericcio sulle libertà costituzionali al tempo del coronavirus,* in *Questione Giustizia,* 2020;

M. Calamo Specchia, *L'autonomia differenziata e la solidarietà interterritoriale: spunti di riflessione per una riforma costituzionalmente sostenibile?*, in *Rivista AIC*, 5/2023;

M. Carrillo, *Diritto di eccezione e sistema costituzionale in Spagna di fronte alla pandemia da COVID-19,* in *Costituzionalismo.it*, 2/2021;

M. Cartabia, *La giurisprudenza costituzionale relativa al secondo comma dell'art 32 cost.*, in *Quad. Cost.*, 2012;

M. Cartabia, *La tutela multilivello dei diritti fondamentali. Il cammino della giurisprudenza costituzionale italiana dopo l'entrata in vigore del Trattato di Lisbona,* Incontro trilaterale tra le Corti costituzionali italiana, portoghese e spagnola a Santiago del Compostela 16-18 ottobre 2014;

M. Cavino, *La natura dei DPCM adottati nella prima fase di emergenza COVID. Lettura di Corte cost. n. 198/2021,* in *Federalismi.it*, n. 25/2021;

M. Cecchetti, *La revisione degli articoli 9 e 41 della Costituzione e il valore costituzionale dell'ambiente: tra rischi scongiurati, qualche virtuosità (anche) innovativa e molte lacune*, in *Forum di Quaderni costituzionali Rassegna*, n. 3/2021, p. 305 ss.;

M. Cosulich, *Equità va cercando… il Servizio sanitario nazionale, strumento di attuazione dell'art. 32 Cost.*, in *Corti Supreme e salute*, 1, 2022;

M. Cosulich, *La rappresentanza degli enti locali. Conferenza o Consiglio?,* in *Le istituzioni del federalismo*, 1, 2001,

M. D'Amico, *Il "fine vita" davanti alla Corte costituzionale fra profili processuali e dilemmi etici (Considerazioni a margine della sent. n. 242 del 2019)*, in *Osservatorio costituzionale*, 1/2020;

M. Di Folco, *La partecipazione delle autonomie territoriali alla determinazione dei livelli essenziali in sanità. Profili sostanziali e procedurali,* in R. Balduzzi (a cura di), *La sanità italiana tra livelli essenziali di assistenza, tutela della salute e progetto di* devolution*,* Giuffrè editore;

M. Di Simone, *L'integrazione del Meccanismo europeo di stabilità e del Trattato "Fiscal Compact" nell'ordinamento dell'Unione europea,* in *Osservatorio costituzionale*, 1, 2018;

M. Di Simone, *Politiche sanitarie in Italia da Crispi a Giolitti. Percorsi di ricerca nelle carte dell'Archivio centrale dello Stato*, in *Popolazione e Storia*, 1/2002, p. 143 ss;

M. Fioravanti, *Appunti di storia delle costituzioni moderne. Le libertà fondamentali,* III ed., Torino, Giappichelli, 2014;

M. Forlivesi, *Next Generation EU: una nuova frontiera dell'integrazione europea,* in *Lavoro e diritto*, 2, 2023;

M. Garrido Falla, *Articulo 43*, en *Comentario a la Constitucion*, Civitas, Madrid, 1980;

M. Gnes, *I limiti del potere d'urgenza*, in *Rivista trimestrale di diritto pubblico*, 3, 2005;

M. Gnes, *La resilienza del sistema sanitario italiano e l'emergenza COVID-19,* in *Global Pandemic Network,* dicembre 2023, vol. 2;

M. Gnes, *La risposta italiana all'epidemia da Covid-19*, in *Giornale di diritto amministrativo*, 3, 2021;

M. Gnes, *Le misure nazionali di contenimento dell'epidemia da Covid-19*, in *Giornale di diritto amministrativo*, 3, 2020;

M. Gnes, *Sanità e assistenza pubblica alla prova della pandemia. L'esperienza italiana*, FrancoAngeli, 2023;

M. Gnes, *Wars and fights against pandemics: there-emerging role of the State as a guarantor of Last resort,* in *European Review of Public Law*, 2022;

M. H. Rodriguez De Minon, *Federlismo asimetrico: il caso spagnolo*, in B. Caravita (a cura di), *Le regioni in Europa. Esperienze costituzionali a confronto. Austria, Belgio, Francia, Germania, Gran Bretagna, Italia, Polonia, Spagna e Svizzera,* Roma, 2002;

M. Iacometti, *La Spagna*, in *Costituzioni comparate*, Giapichelli editore, Torino, 2005;
M. L. Alonso, *La proteccion constitucional de la salud*, La Ley, Wolters Kluwer, Madrid, 2009;

M. Leoy, *Il federalismo belga*, in A. Pace (a cura di), *Quale, tra i tanti federalismi,* 1977;

M. Luciani, *Diritti sociali e livelli essenziali delle prestazioni pubbliche nei sessant'anni della Corte costituzionale*, in *Rivista AIC,* 3, 2016;

M. Luciani, *I diritti costituzionali tra Stato e regioni (a proposito dell'art. 117 comma 2 lett. m) della Costituzione*, in *Politica del diritto*, 3, 2002;

M. Luciani, *Il diritto costituzionale alla salute*, cit., 773;

M. Luciani, *Il diritto costituzionale alla salute*, in *Diritto e società*, 1980;

M. Luciani, *Sui diritti sociali*, in A. Pace (a cura di), *Studi in onore di Manlio Mazziotti di Celso,* Padova, 1995 119 ss.;

M. Manetti, *La cultura dei diritti nell'opera di Alessandro Pace*, in *Dir. Pubbl.*, 2012, 733 ss.;

M. Manganaro, *L'evoluzione del regionalismo differenziato alla luce delle riforme costituzionali. Alcune osservazioni sul punto, in comparazione con il modello territoriale vigente in Spagna*, in *consultaonline*, 3, 2016;

M. Mazziotti di Caleso, *Diritti sociali*, in *Enc. Dir.*, 1964, 806 ss.;

M. Morello, *La tutela della salute e della sicurezza sul lavoro nell'Italia fascista*, in *Quaderni di Diritto della Sicurezza sul lavoro,* 1/2024;

M. Nocelli, *Autorità e libertà nelle decisioni sanitarie tra principio solidaristico e principio personalistico*, in *giustiziaamministrativa.it;*

M. Orofino, *Il territorio di regioni, province e comuni*, in T. Groppi, M. Olivetti (a cura di), *La Repubblica delle autonomie: regioni ed enti locali nel nuovo Titolo V*, Giappichelli editore, Torino, 2003;

M. Rubechi, *Due "nuove" rondini ...fanno primavera? Considerazioni su recenti tendenze del regionalismo italiano,* in *Federalismi*, 10/2021;

M. Rubechi, *I d.P.C.m. della pandemia: considerazioni attorno ad un atto da regolare*, in *federalismi.it*, 27, 2021;

M. Rubechi, *I Decreti del Presidente*, *Studio su d.P.C.m., atti normativi del governo e dinamiche decisionali*, Giappichelli editore, Torino, 2022;

M. Ruotolo, *L'evoluzione delle tecniche decisorie della Corte costituzionale nel giudizio in via incidentale. Per un inquadramento dell'ord. n. 207 del 2018 in un nuovo contesto giurisprudenziale*, in *Rivista AIC*, 2/2021;

M. Salvati, L. Sciolla, *Introduzione*, in Aa. Vv., *L'Italia e le sue regioni,* Treccani, 2015;

M. Salvati, N. Dilmore, *Liberalismo inclusivo. Un futuro possibile per il nostro angolo del mondo,* Milano, 2021;

M. Simoncini, G. Martinico, *Dall'emergenza al rischio nel diritto pubblico comparato: un'introduzione,* in *DPCEonline,* 2022, p. 73;
M. Trapani, *Il sistema delle conferenze e il regionalismo dimezzato: il difficile rapporto tra PNRR e regioni alla luce delle recenti evoluzioni normative*, in *Rivista AIC*, 4/2021;

M.Francaviglia, *Il sistema dei Dpcm al vaglio della Corte costituzionale. Impressioni a prima lettura di Corte cost., sent. n. 198/2021,* in *Diritti Comparati,* 2022;

M.L. Picchio Forlatti, *La sanzione nel diritto internazionale*, Padova, 1974;

M.S. Giannini, *Potere di ordinanza e atti necessitati,* in *Giur. compl. cass. Civ.,* XXVII, 1948;

M.S. Giannini, *Stato sociale*, in *Scritti Mortati*, vol.I, 1977, Milano;

N. Posteraro, *Cure oltre lo Stato: l'effettività del diritto alla salute alla luce del d.lgs. n. 38 del 2014*, in *federalismi.it;*

N. Bobbio, *L'età dei diritti*, Torino, Einaudi, 1990;

N. Lupo, *Il Piano Nazionale di Ripresa e Resilienza (PNRR) e alcune prospettive di ricerca per i costituzionalisti*, in *federalismi.it*, 1/2022;

N. Viceconte, L. Giachi, *La sanità tra Testo costituzionale e interpretazione giurisprudenziali*, in S. Mangiameli, A. Ferrara, F. Tuzi (a cura di), *Il riparto delle competenze nell'esperienza regionale italiana tra materie e politiche pubbliche*, Giuffrè, Milano, 2020;

O. Spataro, *La legge n. 219 del 2017 e la disciplina del fine vita tra principi costituzionali e problemi aperti. Spunti di riflessione,* in *Riv. BioDiritto*, 2019,2;

O. Spataro, *Stato di emergenza e legalità costituzionale alla prova della pandemia,* in *Federalismi*, n. 11/2022, p. 158ss;

P. Caretti, *La Corte costituzionale chiude il caso "Cappato" ma sottolinea l'esigenza di un intervento legislativo sul "fine vita",* in *Osservatorio sulle fonti*, 1/2020;

P. Cruz Villalon, *Estados exceptionales y suspension de garantìas,* Madrid, 1984;

P. De Pasquale, *Le competenze dell'Unione europea in materia di sanità pubblica e la pandemia di Covid-19,* in *DPCE online,* n. 2/2020, p. 2295 ss.;

P. Gaggero, *Programmazione comunitaria per la ripresa e la resilienza nel prisma della solidarietà*, in *Rassegna di diritto pubblico europeo*, 1, 2024;

P. Purnhagen, A. De Ruijter, M. L. Flear, T. K. Hervey, A. Herwing, *More competences than you knew? The Web of Health Competences for European Union Action in Response to the COVID-19 Outbreak,* in *European Journal of Risk Regulation,* Special Issue, 7/2020;

P. Ridola, *Diritti fondamentali. Un'introduzione*, Torino Giappichelli, 2006;

P. Veronesi, *Fisionomia e limiti del diritto fondamentale all'autodeterminazione*, in *Riv. Biodiritto*, 2019 n. 27;

R. Alexy, *Teoria dei diritti fondamentali*, Mulino, 2012;

R. Balduzzi, D. Servetti (a cura di), *La garanzia costituzionale del diritto alla salute e la sua attuazione nel Servizio sanitario nazionale,* in R. Balduzzi, G. Carpani (a cura di), *Manuale di diritto sanitario,* Bologna 2013;

R. Balduzzi, D. Servetti, *Regionalismo differenziato e materia sanitaria*, in *Rivista AIC*, 2019;

R. Balduzzi, *Livelli essenziali e risorse disponibili: un nodo costituzionale?,* in *Scritti in onore di Angelo Mattioni*, Milano, 2011;

R. Balduzzi, *Titolo V e tutela della salute,* in R. Balduzzi, G. Di Gaspare (a cura di), *Sanità e assistenza dopo la riforma del Titolo V,* Giuffrè editore, 2002;

R. Bifulco, *Art. 5*, in R. Bifulco, A. Celotto, M. Olivetti (a cura di), *Commentario alla Costituzione, vol. I,* UTET giuridica, Milano, 136 s.;

R. Bifulco, *Emergenza e considerable weight: il cambiamento climatico nella sentenza klimaSeniorinnen,* in www.lecostituzionaliste.it, 2024;

R. Bifulco, *Federalismo e diritti*, in T. Groppi (a cura di), *La Repubblica delle Autonomie*, Torino, 2001;

R. Bin, *Critica alla teoria delle fonti,* FrancoAngeli, Milano, 2018;

R. Casella, *La Francia dopo gli attentati di Parigi: la dichiarazione dello stato d'urgenza e la proposta di revisione costituzionale del Presidente Hollande,* in *Nomos*, 3/2015;

R. Cavallo Perin, *Potere di ordinanza e principio di legalità. Le ordinanze amministrative di necessità e urgenza,* Giuffrè Milano, 1990;

R. Cisotta, *Principi giurisprudenziali e nuove iniziative della Commissione in materia di patient mobility nell'Unione europea: un piccolo (o grande?) terremoto è in atto*, in *Studi sull'Integrazione europea,* 1, 2007;

R. Ferrara, *L'ordinamento della sanità*, Torino, 2007, p. 39 ss.; C. Bottari, *Tutela della salute e organizzazione sanitaria*, Torino, 2009, p. 15 ss.;

R. Ferrara, *Salute (diritto alla)*, in *Digesto delle discipline pubblicistiche*, vol. VIII, 1997, UTET;

R. Ibrido, *Coordinamento delle decisioni di bilancio e sostenibilità del debito pubblico: ragionando sulla costituzione economica in trasformazione*, in *Rivista Trimestrale di Diritto dell'Economia*, 1, 2020;

R. L. Blanco Valdes, *Los rotros del federalismo*, Madrid, 2012;

R. Nania, *Il diritto alla salute tra attuazione e sostenibilità,* in M. Sesta (a cura di), *L'erogazione della prestazione medica tra diritto alla salute, principio di autodeterminazione e gestione ottimale delle risorse sanitarie*, Rimini, Maggioli, 2014;

R. Mastroianni, *Diritti dell'uomo e libertà economiche fondamentali nell'ordinamento dell'Unione europea: nuovi equilibri?,* in *Il diritto dell'Unione europea*, 2, 2011;

R. Romboli, *Il "caso Cappato": una dichiarazione di incostituzionalità "presa, sospesa e condizionata", con qualche riflessione sul futuro della vicenda*, in *Il Foro italiano*, 6/2019;

R. Romboli, *La Corte costituzionale decide con sentenza il "caso Cappato" e supera l'insormontabile approvando essa stessa la disciplina dell'aiuto a morire*, in *Foro italiano*, 3/2020;

R. Scarciglia – D. Del Ben, *Spagna*, Il Mulino, Bologna, 2005;

R. Virzo*, The proloferation of Institutional Acts of International Organizations – A Proposal for Their Classification,* in R. Virzo, R. Ingravallo (a cura di), *Evolutions in the Law of International Organizations*, Leiden, 2015;

S. Canestrari, *Consenso informato e disposizioni anticipate di trattamento: una "buona legge buona"*, in *Corr. Giur.*, 3/2018;

S. Cecchini, *L'Europa aspira a diventare uno stato sociale?,* in *Rivista AIC,* 4, 2021;

S. Depré, *La cooperation,* in F. Delpérée (a cura di), *La Belgique federal,* 1994;

S. Grassi, *Ambiente e Costituzione*, in *Rivista quadrimestrale di diritto dell'ambiente*, n.
3/2017, pp. 4 ss.;

S. Iaria, *Il potenziale del NRP e del progetto "One Health" nella prospettiva della rivitalizzazione dell'assistenza sanitaria territoriale,* in *Administration on the Way Forum,* 2024;

S. Izzo, *Brevi considerazioni sul ruolo dell'OMS nel contrasto alla pandemia*, in *DPCE online,* 2, 2020;

S. Negri, *La tutela della salute pubblica internazionale tra governance globale, "sovranità sanitaria" e diritti fondamentali*, in *Studi in onore di Augusto Sinagra*, 2013;

S. Negri, *Salute pubblica, sicurezza e diritti umani nel diritto internazionale*, Giappichelli, Torino, 2018;

S. Spatola, *Il solito dilemma: il finanziamento della salute tra effettività della tutela ed esigenze di bilancio. evoluzione, critiche e prospettive alla luce del recente dibattito sociale*, in *Corti Supreme e Salute*, 3, 2023;

S. Staiano, *Salvare il regionalismo dalla differenziazione dissolutiva*, in *federalismi.it*, 7/2023;

S. Van Drooghenbroeck, *L'article 187 de la Constitution,* in *Revue Belge de droit constitutionnel,* 2006;

S. Villani, *The EU Civil Protection Mechanism: instrument of response in the event of disaster,* in *Rivista Universitaria Europea,* 2017, p. 141ss.;

S.R. Vinceti, *La tutela della salute nelle democrazie stabilizzate*, Giappichelli, 2024;

T. Andreani, *Il Servizio sanitario nazionale, tra storia e attualità: riflessioni intorno alla gestazione e alle prospettive di attuazione della riforma della sanità territoriale,* in *BioLaw Journal*, 3, 2023;

T.E. Frosini, *La Costituzione in senso ambientale, una critica,* in *federalismi.*it, 2021;

T.Font y Llovet, *Il processo di "federalizzazione" in Spagna: l'organizzazione amministrativa*, in *Ist. Federalismo*, 1, 2000;

Tornos Mas, *La legislacion basica en la jurisprudencia del Tribunal Constitucional*, in *Revista Vasca de Administracion Publica*, 31, 1991;

U. Adamo, *L'amparo constitucional in Spagna: passato, presente e futuro del ricorso diretto al giudice costituzionale tra natura soggettiva e oggettiva del controllo,* in *Consulta online*, 3, 2015;

V. Crisafulli, *Lezioni di diritto costituzionale,* 1961, Cedam;

V. Fargion, *L'assistenza pubblica in Italia dall'Unità al fascismo: primi elementi per un'analisi strutturale*, in *Rivista trimestrale di scienza dell'amministrazione*, 1983, 30, pp. 25 ss;

V. Gastaldo, *Trattamenti sanitari obbligatori e Costituzione. Il caso della salute mentale*, in *Riv. Biodiritto*, 2/2019;

V. P. Grossi, *La perdurante attualità del regionalismo differenziato. Un'analisi dei contenuti delle bozze d'intesa,* in *Diritti Regionali*, 2, 2021;

V. Piergigli, *L'emergenza Covid-19 in Spagna e la dichiarazione dell'estado de alarma. Ripercussioni sul sistema istituzionale e sul regime dei diritti,* in *DPCEonline*, 2/2020;

V. Tondi delle Mura, *I LEP sulle montagne russe. Primi rilievi sul "Rapporto finale" del Comitato per l'individuazione dei livelli essenziali delle prestazioni*, in *Nuove Autonomie*, 1/2024;

V. Tondi delle Mura, *Non è Voltaire: le pagine bianche (e quelle grigie) del "Rapporto finale" del Comitato per l'individuazione dei Livelli essenziali delle prestazioni*, in *federalismi.it*, 15/2024;

Y. Lejeune, *Droit constitutionnel belge*: *fondements et institutions,* Bruxelles, 2014;