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The Participation of Private Clinics in the Italian National Health System

Abstract: In the Italian healthcare system, private facilities can supplement public ones in delivering services within the framework of the Italian National Health System, provided they meet specific conditions and obtain the necessary authorisations. This set of requirements is known as the 'four As' system, comprising authorisation for the construction of the facility, authorisation to provide healthcare services, accreditation, and contractual agreements. A crucial element in this regulatory framework is the system of tariffs for the remuneration of healthcare services, which are periodically established by the Ministry of Health through a complex procedure. This model of 'administered competition' aims to protect both citizens' health and fair competition among healthcare providers. Proper integration of private facilities into the National Health System is intended to enhance the efficiency of service delivery. The purpose of this paper is to examine the current regulatory framework governing the participation of private clinics in the Italian National Health System and to identify any critical issues.

Keywords: healthcare authorisation, healthcare accreditation, contractual agreements, private clinics, Italian National Health System

Introduction

The Italian health system, through the various evolutions it has undergone over the years, has always aimed at achieving a balance between the various interests involved in the provision of a range of health services. The two main problems that have always characterised this sector are, firstly, the right of Italian citizens to receive qualitatively and quantitatively adequate care, as prescribed by the Constitution (art. 32),

and secondly, the need to safeguard this right in compliance with the duties of containing public spending (art. 97 cost.).

The balancing of these two needs over the years has become increasingly complex due to the growing demand for services (also due to the ageing of the Italian population and increased living standards) and the increasingly stringent public budgetary rules (in addition to the severe strain imposed on state budgets by the recent international financial and pandemic crises). Indeed, the right to health is a fundamental right, but it is also a right that is conditioned by political choices, the availability of financial resources and the way services are organised (Monica, 2023, p. 179). Therefore the National Health System, over the years, has seen the demand for care progressively grow and resources become smaller.

For this reason, since the 1980s, a series of regulatory reforms have entrusted part of the provision of health services to certain private facilities, entrusted with the task of supporting existing public ones. Indeed, Law no. 833 of 23 December 1978 established that a private facility could participate in the provision of health services only if the public system was not able to meet the request for services and subject to a reasoned authorisation by the relevant local health authority. These private facilities were called 'affiliated' (Giustizia Amministrativa, 2010).

Subsequently, the government reorganised the Italian health system through art. 8 of Legislative Decree no. 502/1992, which was subject to numerous amendments and additions in the following years. The founding principles of this reform can be summarised as follows: a) private facilities must have equal conditions in access to the National Health System (the Sistema Sanitario Nazionale or SSN), favouring the principle of citizens' free choice of their place of care; b) in order for a health facility to be able to provide services under the SSN, a procedure based on three phases is provided, through which the facility is authorised to operate under the SSN by meeting certain conditions; c) a system of remuneration for private health services provided at a fixed rate is established, defined by a decree of the Minister of Health, in agreement with the Permanent State–Regions Conference. This 'open' partnership system has, in fact, led over the years to a significant increase in public spending, making health expenditure the largest item of expenditure in regional budgets during the 1990s (Pioggia, 2020, p. 124).

To counteract this trend, Law no. 549 of 28 December 1995 was enacted, which provided for a control mechanism on public expenditure on the provision of health services and a principle for programming the quantity and type of services. In addition, a form of negotiation system was established between public health authoritie and private clinics, through which the maximum limit of public spending was set by the administration. The so-called expenditure ceiling was thus created, to which every single facility (public and private) must strictly adhere. Thus we move from a concept of unlimited and unconditional public assistance to a concept of public assistance with social and health expenditure proportionate to actual revenues. The

health regulation currently in force in Italy is based on the overall reorganisation that took place with Delegated Law no. 419/1998, followed by Legislative Decree no. 229/1999 (and its subsequent amendments), which designed a system where the participation of private providers in the SSN is conditioned to the programming of needs and the availability of regional resources, in order to allow adequate control over public spending. Without claiming to be exhaustive about the evolution of the public–private partnership in the provision of health services, I will try to provide a general picture below of the distinctive features of the administrative process that private health facilities must follow to enter the Italian health system, with a reference to the recent reforms concerning the competitive principles introduced in compliance with European legislation.

1. The 'four As' system for the participation of private entities in the public sector

Currently in Italy, the procedure through which private clinics can operate on behalf of and at the expense of the SSN is divided into four phases that have been described as the 'four As', based on the initial that they share (Pioggia, 2020, p. 125): the phase of authorisation for the construction of the facility; the phase of authorisation to perform healthcare services; the phase of accreditation with the SSN; and finally, the phase of the contractual agreements with the public authority.

The first step is to authorise the construction or extension of hospitals, outpatient clinics or facilities that provide health or social care services on an inpatient basis (including day cases). Such authorisations are issued by municipalities, which are competent in urban planning and construction, after obtaining the opinion of the regional authority in consideration of the location of the facility. Once the building authorisation has been obtained, the facility must obtain the operating authorisation, which is issued either by the regional authority or the municipality, depending on the various regional territories. For the issuance of the latter authorisation, the competent body must verify compliance with the minimum requirements at the structural, technological and organisational levels, in order to verify that health services are adequately guaranteed.

When the facilities have been authorised, if they wish to join the network of facilities that operate on behalf and at the expense of the health service, they must also obtain accreditation and enter into contractual agreements. The accreditation, which is normally issued by the regional authority, consists in the verification of compliance with additional requirements (with respect to those prescribed for the authorisation) and the verification of the functionality of the facility (with respect to national and regional programming). Finally, the accredited clinic must enter into agreements with the regional administration regarding the volume of services that each facility

undertakes to provide at the expense of the regional health service, and the related remuneration.

Therefore, after obtaining the two former authorisations, the facility may be considered authorised to carry out health services, but not to provide them in the framework of the SSN. With the accreditation, the facility may be considered suitable, that is, a potential provider of health services under the public system. But it is only with the stipulation of contractual agreements that the facility acquires the status of a subject authorised to carry out healthcare operations at the expense of the SSN.

2. Authorisation to build facilities and conduct operations

The institution of authorisation is governed by art. 8(3) of Legislative Decree no. 502/1992, which provides for a standardised regulation for the issuance of the two aforementioned authorisations, namely for the construction (or expansion) of a facility and for conducting healthcare activities. As mentioned, mere authorisation does not imply the performance of services under the SSN; it must also be obtained by any clinic that intends to provide health services even if only privately, without carrying out the subsequent phases of accreditation and stipulation of contractual agreements.

Art. 8(3)(1) specifies that such authorisations are necessary for clinics that provide services on an inpatient basis, clinics that provide specialist care services on an outpatient basis (including rehabilitation and instrumental and laboratory diagnostics) and health and social care facilities that provide services on an inpatient, continuous cycle or day-case basis. The following paragraph, on the other hand, identifies certain facilities for which it is necessary to obtain only authorisation to carry out activities but not authorisation to construct. Such facilities include dental, medical and other healthcare clinics, if they are equipped to provide outpatient surgery or diagnostic and therapeutic services of particular complexity, as well as home care. The following paragraphs of art. 8(3) define the methods of and requirements for obtaining the two authorisations.

The procedure for authorising the construction of a clinic begins with the submission of an application to the relevant body of the municipality where the clinic has (or will have) its headquarters, accompanied by a related working plan. The municipality must then request the regional administration to verify the compatibility of the project with the regional plan, which must be related to the overall needs and territorial location of the facilities present in the area, also in order to best guarantee accessibility to services by users. Considerable criticism has been expressed by jurisprudence on the issue of such authorisations, owing to the difficult balance between private and public interests, i.e. the constitutional principle dictated by art. 41 of the Constitution, according to which 'the private economic initiative is free', and the right to health protected by art. 32 of the Constitution (Giustizia Amministrativa, 2020).

With reference to a request for authorisation to carry out health activities, it is prescribed that the clinic must meet the minimum structural, technological and organisational requirements established by law through official guidelines subject to regular updating. On the other hand, regarding the type of power exercised in the issuance of authorisation for these activities, it must be considered that the public administration does not actually have the discretion to decide, as the issuance of the authorisation is subject to the mere verification of compliance with the requirements (Pioggia, 2020, p. 126).

3. Healthcare accreditation and contractual agreements

When authorisation to operate has been obtained (and therefore when the possibility of providing private health services has been admitted), the organisation can decide to submit an accreditation application with their relevant regional authority. Through accredited private health facilities, regional authorities guarantee the provision of health services using qualified private organisations (Bocale, 2018, pp. 2–3; Cuttaia, 2020, p. 2). The accreditation is the recognition of the possession of specific requirements (so-called qualification standards), in the presence of which healthcare professionals can be included in the national healthcare system and can be chosen by the users of healthcare services (Cauduro, 2023, p. 19). Accreditation can therefore be defined as a compulsory qualification for facilities that wish to provide services paid for by the SSN. The institution of accreditation is governed by art. 8(4) of Legislative Decree no. 502/1992. Obtaining it is subject to technical requirements further to those mandated for the authorisation; the fact that the applicant organisation is functional 'to the regional planning guidelines'; and finally, the 'positive verification of the activity carried out and the results achieved' (Caruso, 2017, p. 161).

According to the general approach of the state regulations, health (and social care) accreditation is closely linked to planning choices, as a measure that governs the function of quotas and selection when joining the SSN. In other words, not all private operators that meet the technical requirements are entitled to obtain it, but only those whose activity is appropriately included in regional planning. The link between accreditation and planning therefore implies some room for discretion on the part of the administration in terms of assessing compliance with the objectives of programming (Giustizia Amministrativa, 2009). Therefore, pursuant to art. 8(4) of Legislative Decree no. 502/1992, the issuing of institutional accreditation by the relevant region is subject to a) 'compliance with the additional qualification requirements'; b) 'private operators functionality with respect to the regional programming guidelines'; and c) 'positive verification of the activity carried out and the results achieved'.

The achievement of the status of accredited organisation is necessary but not sufficient to make a private organisation a provider of health services paid for by the

SSN. To this end, a further final step is necessary, which is the signing of the contractual agreement governed by art. 8(5) of Legislative Decree no. 502/1992. In this regard, however, it should be pointed out that the stipulation of a contractual agreement does not derive from real bargaining, given that not only is the maximum volume of services established unilaterally by the administration when planning, but also the reference territory and the category of services requested are external factors that cannot be negotiated (D'Angelosante, 2012, p. 260).

Precisely because of this particularity, an element that qualifies this type of contract is the fact that in recent years, the contractual agreement has featured a so-called safeguard clause, i.e. a clause by which the accredited private contractor undertakes to waive any disputes already in progress or future ones relating to the so-called expenditure ceilings or other related acts. This clause has been submitted to the scrutiny of an administrative judges several times, who has considered it legitimate, and as conclusively decided by the Council of State, according to which the clause appears perfectly consistent with the new conception of good performance, in a financial and economic sense (Giustizia Amministrativa, 2017). The administrative judges have, in essence, traced the clause in question back to a contractual regulation, left to the contractual autonomy of the parties (public and private), who are not at all 'forced' to accept it, given that the alternative for private facilities would be to remain in the free market and, for the public party, to refuse to purchase health services under conditions that are not consistent with its own planning and financial resources.

4. Rates for the remuneration of services

Regarding the planning and control of health expenditure, Legislative Decree no. 502/1992, art. 8(5), aimed to regulate the remuneration of health services provided by the SSN, which 'are financed according to a predefined global amount specified in the contractual agreements referred to in art. 8(5) and determined based on the care functions and activities carried out within and on behalf of the network of reference services'. The list of services provided by the SSN and their individual remuneration therefore constitute an official regional tariff list for specialist outpatient services.

The procedure for the calculation of rates is provided for by paragraph 3 of art. 8(6) of Legislative Decree no. 502/1992, according to which 'the general criteria for the definition of the maximum remuneration for the services are established by a specific decree of the Minister of Health, after consulting the Agency for Regional Health Services, in agreement with the Permanent Conference for the relations between the State, the Regions and the Autonomous provinces'. The maximum remuneration rates are thus established, to be paid to the accredited organisations based on standard production costs and standard shares of overhead costs, calculated based on a representative sample of accredited clinics. The reference legislation also provides

for an update of such rates every three years, through specific agreements, with the participation of the Ministry of Health and Regions (Law no. 311/2004, art. 1(170)). The tariff system must be applied together with the expenditure limits on the one hand and the expenditure ceilings of the individual facilities on the other. This constitutes a barrier and a guarantee of the maximum spending limit.

However, the pricing system has always created considerable friction between the public party (the Ministry) and private parties (accredited organisations), due to the complexity of the pricing determination procedure, as well as its supposed uneconomical nature (according to the private providers), which is allegedly due to the failure to apply the pricing terms provided for by the aforementioned legislation. By way of example, the decree of the Ministry of Health of 22 July 1996, containing the official tariff list for that year, was annulled by the Council of State on the assumption that 'the procedure followed does not meet the basic criterion by which the determination of individual rates must result from a significant sample of public and private facilities, so as to verify the necessary logical connection between the assessment of costs and pricing' (Giustizia Amministrativa, 2001).

The rationale of the regional tariff lists has been clarified several times by administrative jurisprudence that has defined their character as 'exceptional and temporary […] inspired by reasons of containment of health expenditure and the need to establish, throughout the national territory, uniform rates in a short time' (T. A. R., 2013; confirmed on appeal by Giustizia Amministrativa, 2014). The new national tariff list entered into force on 1 January 2025, by application of the decree of the Ministry of Health of 23 June 2023 containing a definition of the rates for outpatient and prosthetic specialist care, which, however, has been the subject of multiple appeals by the trade associations of accredited private organisations and is still pending.

5. Competition among accredited healthcare organisations

As mentioned above, the healthcare sector must find a balance between the constitutional principles that underlie the protection of citizens' health (art. 32 of the Constitution) and the freedom of private economic initiatives (art. 41). This balance also necessarily includes the protection of competition, which should exist above all for the efficiency of the service rendered. That is why, in this regard, we talk about 'administered competition' (Caruso, 2017, pp. 166–167). The administered competition regime has the dual function of safeguarding a citizen's freedom of choice regarding their place of care (in particular, whether to use public or private facilities) and at the same time of ensuring adequate levels of quality in private healthcare (and social care) facilities (Cuttaia, 2023, p. 46). Therefore, on the urging of the Competition and Market Authority (Autorità Garante della Concorrena e del Mercato, 2021) and of jurisprudence (Judgment of the Constitutional Court, 2005), lawmakers have

recently introduced significant innovations to protect competition among private health facilities joining the SSN by adopting the 2021 Annual Law for the Market and Competition (no. 118/2022). Article 15 of this law, in fact, modified the system of institutional accreditation and that of agreement with private providers, establishing – in Article 8-quater, paragraph 7, legislative decree no. 502/1992 – the abolition of the institution of provisional accreditation and the provision that, in the case of requests for accreditation of new facilities, the following criteria should be taken into account cumulatively: (i) quality and volume of the services to be provided; (ii) results of any activities already carried out; (iii) results of control, supervision and monitoring activities for the evaluation of the activities provided in terms of quality, safety and appropriateness.

This amendment was followed by the Decree of the Minister of Health of 19 December 2022, containing an 'evaluation in terms of quality, safety and appropriateness of the activities provided for accreditation and contractual agreements with health facilities'. The implementation of the provisions set forth in this decree, first scheduled for 1 January 2023, has been repeatedly postponed due to evident difficulties of its application by the regions, and is now scheduled for 31 December 2026. Articles 2 and 3 of this decree provide respectively for the evaluation criteria for the issuing of new accreditations as well as the evaluation of the activities of (accredited) private entities interested in entering into contractual agreements.

In my opinion, this ministerial decree contains certain critical aspects that may create application problems after its entry into force. Firstly, the decree has been established that in order to conclude the contractual agreements, it is necessary to proceed with 'the publication of a notice containing objective selection criteria, which prioritise the quality and minimum volume of the specific services to be provided'. The prioritisation of volume (among the evaluation parameters) provides, at least potentially, an advantage for larger facilities in the comparative procedure, thus creating difficulties for smaller organisations, which, however, are numerically in the majority in the country. Moreover, the concentration of the offer in the hands of a limited number of facilities would entail a significant decrease in providers and a simultaneous centralisation of the supply, putting at risk the local or 'territorial' character of the provision of services across the country. It will therefore be appropriate for regional administrations to find a balance in the prioritisation of the parameters (including the volume delivered).

A second critical issue concerns the general guidelines on the frequency with which regional administrations must proceed with the publication of notices. The frequency with which the comparative procedures are carried out will have a great impact on the economic management of private providers. Indeed, too high a frequency would entail a risk of instability for these organisations, depending on whether they obtain the contract (and therefore a budget) or not. In turn, this lack of certainty would discourage

these organisations from making economic investments for the purchase of equipment or, more generally, for the qualitative improvement of services.

Finally, one last critical issue – although not connected to the decree of the Ministry of Health – concerns the exclusion of health services from the scope of the Bolkestein Directive, article 2(2)(f). Therefore, although the intention of the Italian legislature to guarantee an open and competitive health market to private providers is acceptable, the generic nature of the ministerial decree is a risk that could lead, in different actions by individual regions, to configurations that would jeopardise the sustainability of the system as a whole.

Concluding remarks

The evolution of the Italian health system, with the inclusion, through the measures of accreditation and contractual agreements, of private providers alongside public ones in the provision of healthcare (and social care) services, has pursued the dual objective of safeguarding Italian citizens' freedom of choice of their place of care as well as meeting the growing demand for medical examinations and health services. The correct balance between public and private provision of services should guarantee better efficiency in both the quality and the timeliness of the services of the SSN. Indeed, to date, one of the main features of the Italian health system is the wide range of services provided, with charges borne by the SSN, and the number of facilities available across the territory.

However, as we have seen, the appropriate remuneration of accredited private facilities and the remuneration of competition (both among themselves and with public facilities) may lead to significant changes in the operation of the system and the provision of services in the near future. Therefore careful activity from governments and the legislature will be necessary to guarantee uniformity in provision, albeit within the framework of the constitutional autonomy granted to the regional systems that will find themselves increasingly in (virtuous) competition with each other and in the simultaneous application of increasingly stringent budgetary constraints. The proper, gradual and well-managed inclusion of private health providers in the SSN must constitute an incentive for regional health services to pursue the due efficiency objectives, also through monitoring of the quality and efficiency of public and private healthcare provision.

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