

**ACCREDITATION IN HEALTHCARE: NATIONAL STANDARDS
AND REGIONAL IMPLEMENTATION**

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1. INTRODUCTORY REMARKS.

Accreditation is an assessment of the quality of a service, of goods or of an activity, and consists of a process that checks compliance with predetermined standards.

The interest in assessing quality arises in competitive environments, as an answer to a request for correct and prompt information that usually originates from consumers or

users. Usually, the initial impulse for assessment stems from private actors who are interested in certifying quality and who are consequently ready to bear the costs of the assessment process. More and more frequently, though, when public agencies also become interested in certification, they choose to rely on private assessment, by taking advantage of private accreditation.¹

Consequently, and as a result of the global increase in exchanges in almost every economic activity, accreditation is now widespread across many sectors.

Nevertheless, its scope and objectives may vary widely, sector by sector.²

Specifically, accreditation in the healthcare sector rests upon a threefold set of purposes. First, accreditation embodies the interests of patients, who wish to be correctly informed mainly about the safety of the service provided by healthcare givers but also about its quality. Secondly, accreditation advances the interests of providers, who wish to provide quality assurance in order to attract more patients. A third objective is related to the public need to ensure compliance with predetermined minimum levels of healthcare. This happens specifically when both private and public providers are operating within the public healthcare system and when services are mainly financed by public funds.

The idea behind this essay is the following: accreditation was transplanted into the Italian healthcare system in 1992, mainly to ensure healthcare quality and safety, but during the final decade of the last century accreditation rapidly turned into a regulatory device

¹See, for instance, Regulation (EC) no 1060/2009 of the European Parliament and of the Council of 16 September 2009, on credit rating agencies; Regulation (EU) no 462/2013 of the European Parliament and of the Council of 21 May 2013 amending Regulation (EC) No 1060/2009 on credit rating agencies.

² The use of standards and certifications as a mechanism for sector-specific regulation is widespread in the global environment: on this issue, see K. Davis, A. Fisher, B. Kingsbury, S. Engle Merry (eds.), *Governance by Indicators. Global Power through Classification and Rankings*, Oxford University Press, Oxford, 2012.

after being re-shaped to serve the planning of healthcare and the control of public expenditure.³

The transition described above took place through a series of reforms that was approved during the 1990s. In the regime that entered into force in 1999, the legal definition of accreditation became more controversial.⁴ This ambiguity was noted both in scholarly writings and in judicial rulings.⁵

³ On this issue, see V. Molaschi, *Autorizzazione, accreditamento e accordi contrattuali tra esigenze di contenimento della spesa pubblica e tutela della concorrenza*, in *Giur. it.*, 2014, p. 657 ff.; Autorità garante per la concorrenza ed il mercato, AS175 Parere 19 maggio 1999, n. 175, in *Bollettino*, 1999, n. 18; Autorità garante per la concorrenza ed il mercato AS852 18 luglio 2011, in *Bollettino*, 2011, n. 27; AS1037 – Regione Lazio – rilascio autorizzazioni all'esercizio e alla realizzazione di strutture sanitarie private, in *Bollettino*, 2013, n. 13. The procedure, started in 2005, still has not been brought into a conclusion: see IC30 - settore delle prestazioni sanitarie ospedaliere, Provvedimento n. 14389, 2005.

⁴ In the so called “*Disciplinare per la revisione della normativa dell’accreditamento*”, approved by Agreement within the Italian *Conferenza permanente per i rapporti tra lo Stato, le Regioni e le Province Autonome*, the different objectives look inverted: «l’accreditamento, oltre ad avere una funzione regolatoria, è uno strumento di garanzia dei livelli di qualità delle strutture sanitarie e socio-sanitarie». See Conferenza permanente per i rapporti tra lo Stato, le Regioni e le Province Autonome, Agreement, December 20, 2012 (Rep. Atti. 259), *allegato A*, § 1, at the following link: http://www.statoregioni.it/Documenti/DOC_038866_259%20csr%20-%204.pdf.

⁵ On the legal status of accreditation in health care, see A. Quaranta, *L’accreditamento come atto di abilitazione nel Servizio Sanitario Nazionale*, in *L’Accreditamento è un diritto?*, V. Bellini and E. Paolini (eds.), Roma, 2003; C. Corbetta, *La sanità privata nell’organizzazione amministrativa dei servizi sanitari*, Rimini, 2004, p. 211 ff.; E. Jorio, *L’accreditamento istituzionale e il ruolo del privato nell’organizzazione della salute*, in *San. pubbl. e priv.*, 2004, p. 151 ff.; G. Cilione, *Diritto sanitario. Profili costituzionali e amministrativi, ripartizione delle competenze, organizzazione, prestazioni, presidi sanitari privati, professioni*, Rimini, 2013, p. 229 ff.; G. Tansarella, *Sistema sanitario e accreditamento: il dovere di reciproca lealtà* (Tar Campania, Napoli, I, 11 febbraio 2002), in *Foro amm. Tar*, 2002, p. 619 ff.; V. Molaschi, *Tutela della concorrenza, vincoli di spesa e rapporti tra servizio sanitario nazionale e soggetti privati: una riflessione alla luce della riforma del titolo V della Costituzione* (Tar Lombardia, Milano, I, 29 ottobre 2003, n. 4899), in *Foro amm. Tar*, 2004, p. 1271 ff.; F. Gigliotti, *Ritardo nel pagamento dei corrispettivi di prestazioni sanitarie rese da strutture accreditate e applicabilità del d. lgs. 231/2002*, in *I Contratti*, 2014, p. 57 ff.

The uncertain legal meaning of accreditation has implications for the implementation regime. The importance of this issue for the current management of our national healthcare system is confirmed by the continual interventions of the legislator. That is why we have decided to discuss accreditation in healthcare, focusing on its implementation.

To begin with, we discuss below three legal provisions taken from distinct legal orders. Our purpose is to highlight the fact that the different definitions given for accreditation all prove how controversial is its legal status.

In the *Memorandum and Articles of Association*, published by the *International Society for Quality in Healthcare Limited (ISQua)*, accreditation is defined as “[a] public recognition of the achievement of *standards* by an organization demonstrated through independent assessment in relation to set *standards*”.⁶

Art. 8 *quater* of the Legislative Decree of December 30, 1992, n. 502, states that accreditation is issued to providers upon request, provided that they comply with additional standards, and adhere to regional health planning Acts, and is given after a positive check of a provider’s performance: “[l]’*accreditamento istituzionale è rilasciato dalla regione alle strutture autorizzate, pubbliche o private ed ai professionisti che ne facciano richiesta, subordinatamente alla loro rispondenza ai requisiti ulteriori di qualificazione, alla loro funzionalità rispetto agli indirizzi di programmazione regionale e alla verifica positiva dell’attività svolta e dei risultati raggiunti*”.

A further Act, taken as an example from the region of Basilicata, states that institutional accreditation is a process, connected to regional healthcare planning, through

⁶ See the following url: <http://www.isqua.org/docs/constitution-and-policy-documents/isquamandacurrent856EF1AEB6C4.pdf?sfvrsn=2>.

which, as an administrative act, healthcare givers are entitled to operate within the public regional healthcare system.⁷

Some general remarks may be pointed out from a first analysis of the three definitions listed above.

The definitions certainly refer to different institutional and legal contexts, and they address different forms of accreditation. While the first definition refers to private accreditation, the second and third address the public certification that is considered necessary in order for a body to be entitled to operate within the public regional health system.

Nevertheless, the different views expressed by the three definitions also prove that accreditation may be vested with different meanings. They suggest that a transition has been experienced thus far within the Italian healthcare system. In the health system as it was at the beginning of the 1990s, there was open access for providers⁸ on the basis of the recognition of their freedom to do business: accreditation was a licence. The regime in

⁷ See *Allegato I*, Executive Board Decree, Basilicata, December 30, 2005, n. 2753, which literally states: «è il procedimento attraverso il quale, a conclusione di uno specifico processo valutativo ed in relazione agli indirizzi della programmazione regionale, viene attribuito alle strutture sanitarie già in possesso dell'autorizzazione all'esercizio, e che ne facciano richiesta, lo status necessario per diventare soggetti erogatori per conto del servizio sanitario regionale (SSR), previo riconoscimento di specifici requisiti di qualità sul piano tecnologico, organizzativo e professionale, ulteriori rispetto a quelli richiesti per l'autorizzazione all'esercizio dell'attività». Specifically, attention to quality is paid in Regional Law (hereinafter r.l.) Veneto, February 7, 2014, n. 2, *Disposizioni in materia di promozione della qualità dell'assistenza sanitaria, socio-sanitaria e sociale e modifica della legge regionale 16 agosto 2002, n. 22 "Autorizzazione e accreditamento delle strutture sanitarie, socio-sanitarie e sociali"*; r.l. Toscana, October 17, 2012, n. 57, *Modifiche alla legge regionale 5 agosto 2009, n. 51 (Norme in materia di qualità e sicurezza delle strutture sanitarie: procedure e requisiti autorizzativi di esercizio e sistemi di accreditamento)*.

⁸ B. Bonvento, *La misurazione dell'impatto delle procedure di autorizzazione e accreditamento*, in *San. pubbl. e priv.*, 2006, p. 32 ff.

place at the end of the 1990s, as a result of the reforms that took place mainly in 1999, took a different view of the legal nature of accreditation,⁹ and accreditation became a concession.

The three definitions also highlight the distinction between voluntary and institutional accreditation, which arises from the transition described above.

As already mentioned, accreditation originates in healthcare systems, where it is vested initially with a voluntary character, and where compliance with safety and quality standards is acknowledged mainly by peers that are private institutions. Once transplanted into our healthcare system, the legal instrument that we now describe as institutional accreditation, without losing the part of its original character that relates to quality standards, is also used for planning healthcare, distributing resources, regulating healthcare providers and controlling public expenditure.

This essay aims to discuss the multiple facets of accreditation in the Italian healthcare system.

By virtue of the concurrent legislative competence of the state and the regions, this investigation not only addresses the national system for accreditation, but also examines the implementation of accreditation within the regional healthcare regimes.

With this purpose, we carry out an analysis of recent regional policies and regulations. In addition, we make use of data published by the *Agenzia nazionale per i servizi sanitari regionali* (National Agency on Regional Healthcare Systems) in its most recent report on the implementation of the accreditation regime at the regional level.

Because of the scope and the nature of this essay, we do not differentiate among classes of providers: in other words, divergences among accreditation regimes for

⁹ On this issue, C. Bottari, *Tutela della salute ed organizzazione sanitaria*, Torino, 2009, p. 96 ff.

ambulatory healthcare, hospitals, home healthcare, laboratories, and critical access hospitals are left in the background at this stage of our research.¹⁰

The analysis of the normative evolution, which is aimed at assessing the implementation of the accreditation system by the regions, has a specific relevance. Parallels and differences may help in interpreting regional systems, by putting the accent on regional choices about factors of enormous significance in order to assess the state of our healthcare system. We refer here to the resultant mix between public and private providers, to the effects of budgetary control, and to the strategies in place to guarantee free choice to patients, safety in healthcare and services of good quality.¹¹

The investigation is structured as follows. After some short preliminary remarks on private assessments, we focus on institutional accreditation. In this regard, we first discuss the normative framework, at both the national and the regional level. Secondly, parallels and differences between regional systems are highlighted. Thirdly, forms and stages of the implementation process are pointed out. Lastly, some concluding remarks are set forth, which also refer to budgetary constraints over public expenditure and to the implications of these within those regional systems that are subject to governmental financial control within our legal system.¹²

¹⁰ On which, see paragraph 4(f), art. 8, Legislative Decree (hereinafter lgs.d.) n. 502/1992.

¹¹ For updated data on the Italian Healthcare System, see Istat, *Rapporto annuale*, Roma, 2014, specifically chapter 4.2, *Il Sistema sanitario nazionale: un difficile equilibrio tra efficienza e qualità*, p. 168 ff.

¹² On this issue, see A. Nardone, *La distribuzione dei poteri in sanità: le ipotesi di sostituzione del Governo nella gestione delle politiche di spesa nelle regioni*, Napoli, 2009. On healthcare sustainability, M. D'Angelosante, *Strumenti di controllo della spesa e concorrenza nell'organizzazione del servizio sanitario in Italia*, Rimini, 2012; R. Nania, *Il diritto alla salute tra attuazione e sostenibilità*, in M. Sesta (ed.), *L'erogazione della prestazione medica tra diritto alla salute, principio di autodeterminazione e gestione ottimale delle risorse sanitarie*, Rimini, 2014, p. 29 ff.; G. Ceresetti, "Spending review", *accreditamento sanitario e proposta di legge n. 4269 del 2011: una riforma possibile per la remunerazione delle prestazioni?*, in *Foro amm. Tar*, 2012, 9, p. 2987 ff.

2. ACCREDITATION BY PRIVATE PARTIES: INTERNATIONAL ACCREDITATION UPON REQUEST

Accreditation in healthcare originates from the need to ensure minimum standards for safety, but it becomes a widespread need when providers voluntarily decide to be subject to external scrutiny by peer institutions in order to pursue optimal quality standards.¹³

The need for quality and safety measurements stems mainly from health systems in which private and public providers are both providing care and working in a competitive environment.¹⁴ Originally, and usually, standards are set by private setters, while tasks related to the accreditation process are entrusted to private agencies, formally independent from the providers and regulators.

Within the contexts described, private accreditation fulfils two purposes: on the one side, it favours providers that wish to prove their qualities, while, on the other side, it operates as a form of guarantee for patients, by directing them towards safe choices or simply by supporting them in their aim to choose quality.¹⁵

¹³ See the definition adopted by the *American College of Surgeons* in 1919, within the *Hospital standardization program*, so called *The 1919 minimum standard document*, in *General Hospital of 100 or more beds*, in American College of Surgeons, *Bulletin*, IV, n. 4, 1920, at the following link: <https://www.facs.org/about-acs/archives/pasthighlights/minimumhighlight>.

¹⁴ On accreditation systems, under a comparative perspective, see M. Consito, *Accreditamento e terzo settore*, Jovene, Napoli, 2009; G. Cerrina Feroni, *Pubblico e privato nella erogazione delle prestazioni sanitarie. Italia, Germania, Svizzera a confronto*, in *Munus*, 2012, p. 1 ff.; E. Robotti, *Ssn e standard di qualificazione accreditamento dei servizi sanitari*, in *Contratti*, 2004, p. 1048 ff.; A. Pioggia, S. Civitarese Matteucci, G.M. Racca, M. Dugato (eds.), *I servizi sanitari: organizzazione, riforme e sostenibilità. Una prospettiva comparata*, Torino, 2011.

¹⁵ On accreditation in other sectors see, recently, A. Moscarini, *L'accreditamento nel regolamento Ce n. 765/2008 e le "fonti" di produzione privata*, in *Rivista di Diritto Alimentare*, 2012, 1, p. 18 ff.; A. Benedetti, *Profili di*

This happens in the United States, for instance, where the Joint Commission is a not-for-profit organization that assesses providers on demand and that acts through periodical audits aimed at checking compliance with privately determined standards.

Forms of accreditation that now tend to prove qualities of excellence are addressed within the Italian legal order as “*accreditamento di eccellenza*”. This label distinguishes this kind of accreditation from the institutional one that operates within the public healthcare system. In this latter case, accreditation measures compliance with general minimum standards set at the national level and with additional standards set by the regions. Compliance with requirements is due from both public and private providers if they wish to be considered as part of the National Health System (hereinafter NHS) and to be paid from public funds for providing care services.

Nevertheless, even if not specifically required at the national level by the legislation on accreditation, many regions consider forms of international or private certification as additional standards for institutional accreditation. Private certifications are rarely seen as a minimum standard for institutional accreditation; most frequently they represent a requirement for subsequent additional public benefits. Within this trend, in particular, some regions have incorporated the standards issued by the Joint Commission as additional criteria for public accreditation,¹⁶ some have made reference to international standards for accreditation, as additional standards set out at the regional level (as in the Sardinia region, in the *Piano regionale dei servizi sanitari* approved on January 19, 2007),

rilevanza giuridica delle certificazioni volontarie ambientali, in *Rivista quadrimestrale di Diritto dell'Ambiente*, 2012, 1-2, p. 20 ff.; M. De Bellis, *Certification and climate change. The role of private actors in the Clean Development Mechanism (CDM)*, in *Riv. it. dir. pubbl. comun.*, 2012, p. 759 ff.; C. Barbati, *La Valutazione del sistema universitario*, in *Giorn. dir. amm.*, 2012, p. 816 ff.

¹⁶ See Lombardia, d.g. sanità, *La valutazione delle aziende sanitarie in Regione Lombardia*, January 14, 2010, at the following url : http://www.salute.gov.it/imgs/C_17_newsAree_848_listaFile_itemName_14_file.pdf.

others have added certifications by private agencies to the accreditation process,¹⁷ or done the same with the certification processes set out by general disciplines, such as ISO 2000 (which is included, for instance, within the Liguria accreditation programme),¹⁸ and yet others ask for certifications by qualified experts.¹⁹ In other regions, moreover, international accreditation represents a factor for giving providers different levels of accreditation.²⁰ The regional law approved by the Molise region, dated June 24, 2008, n. 18, art. 18, for instance, considers international accreditation as best practice for both private and public providers.

If, in some cases, international accreditation is taken into consideration as an additional label concerning quality, in others, surprisingly, excellence acknowledgments do not count for so much, especially when there are financial constraints on the selection of those providers who, following institutional accreditation, will be part of the NHS. In most cases, in fact, the rationale behind such determinations may depend on other criteria. Nevertheless, the weight of private/international accreditation as a useful standard for

¹⁷ See Umbria, Regional Executive Board Resolution (hereinafter r.b.r.), May 7, 2003, n. 570, *Approvazione del Modello operativo per l'Accreditamento Istituzionale delle strutture sanitarie e socio-sanitarie*.

¹⁸ See r.b.r. Liguria, April 29, 2002, n. 395, *Approvazione procedura e istanza per la richiesta di accreditamento dei presidi sanitari e socio-sanitari pubblici e privati, versione aggiornata del "Manuale per l'accreditamento" nonché disposizioni relative all'avvio dello stesso*.

¹⁹ See § 2.10, r.b.r. Emilia Romagna, February 23, 2004, n. 327. See also Agenzia sanitaria e sociale regionale, *L'accreditamento istituzionale delle organizzazioni sanitarie e dei professionisti in Emilia-Romagna. Sviluppo e sperimentazione di metodologie per la qualificazione di valutatori idonei a svolgere attività di verifica delle strutture sanitarie a scopo di accreditamento e ad affiancare in qualità di esperti tecnici di settore valutatori di sistemi qualità per la certificazione (anni 1997-2000)*, at the following url: http://www.regione.emilia-romagna.it/agenziaasan/aree/accred/accreditamento/progr_qualificaz_valutatori.htm.

²⁰ See r.b.r. Basilicata, July 1, 2008, n. 591/P; Provincial Executive Board Resolution (hereinafter p.b.r.) Bolzano, March 17, 2003, n. 763, *Approvazione dei requisiti minimi e ulteriori per l'autorizzazione e l'accreditamento delle strutture sanitarie ospedaliere e assimilabili*.

institutional accreditation can be assessed by analysing regional healthcare planning Acts and regulations on accreditation.

Whether or not private/international accreditation is incorporated into regional additional standards for institutional accreditation, providers more and more frequently seek to obtain it for their own reputation.

As already mentioned, particularly relevant in this field is the activity of Joint Commission International. Founded in 1994 by the US Joint Commission, this not-for-profit agency is based in Illinois and has subsidiaries in Singapore and Dubai. Joint Commission International has accredited 24 Italian providers so far.

The Joint Commission is part of the International Society for Quality in Healthcare (ISQua), a not-for-profit association based in Dublin, whose main aim is to promote quality in healthcare services through accreditation, and whose main tasks consist, on the one hand, in issuing certifications for providers and, on the other hand, in assessing certificatory bodies themselves.

The widespread success of the Joint Commission activity shows a clear tendency toward a culture of certifying quality.

Furthermore, attention to accreditation as well as to the regional affirmation of accreditation mechanisms is about to acquire even more relevance by virtue of the approval of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare.

In order to give patients more choice, more information must necessarily circulate and, as well, more common standards, especially on quality and safety, must be adopted. In this regard, both the Directive and the legislative decree of March 4, 2014, n. 38, which transposes it into the Italian legal order, at art. 7 and art. 9, paragraph 6(c), include the following information that the national contact points are responsible for circulating: first, information on standards and guidelines; second, information on the supervision and assessment of healthcare providers; third, information on providers that are subject to the

standards; and fourth, guidelines and information on the accessibility of hospitals as well as conditions for the safety and quality of the healthcare providers. It is useful to remind ourselves that most of these information requirements are considered as essential preconditions for reimbursement, and must be complied with under the supervision of the national contact point.

3. INSTITUTIONAL/PUBLIC ACCREDITATION

In a different way from private/international accreditation, which has a mainly voluntary basis, institutional/public accreditation is compulsory for all public providers, as well as for private providers wishing to operate within the NHS. Accreditation is required both for incumbents, namely for healthcare providers formerly authorized within the previous regime for access to the healthcare sector, and for new entrants, namely for healthcare providers interested in starting to operate within the NHS.

Whatever the regional healthcare system, as already mentioned, the requirement for institutional/public accreditation arises not only from the need to prove the quality of healthcare providers but also from the need for a strict control of public expenditure and the use of public resources. That is the main reason why it is not only private providers that are required to obtain accreditation, but also public ones.

In the same way as any other administrative act, accreditation follows an administrative procedure that is part of a more complex sum of connected but distinct procedures aimed globally at allowing providers to operate within the NHS.²¹

²¹ On this issue, see F. Taroni, *Le 3A: autorizzazione accreditamento, accordi contrattuali*, in *Manuale di diritto sanitario*, R. Balduzzi and G. Carpani (eds.), Bologna, 2013, p. 427 ff.

²¹ On this issue, with specific reference to interactions among proceedings, see R. Spagnuolo Vigorita, *Politiche pubbliche del servizio sanitario. Profili giuridici*, Napoli, 2003.

The so-called 3A process to enter the healthcare sector consists of an authorization procedure/act, an accreditation procedure and an agreement. Within this sequence, the authorization process allows providers to perform healthcare activities; the procedure for accreditation entitles providers to act within the NHS; and the agreement sets concrete conditions for the provision of healthcare financed by public funds.

The relationships between these different procedures and the interactions among their results have been discussed by legal scholars, as well as by judges, with controversial results so far.²²

Specifically, the private/public nature of providers has profoundly influenced the discussion and the description of accreditation.²³ Moving on from this aspect, the jurisprudence has described accreditation as a concession for private providers and as an organizational act for public ones.²⁴

The importance of the definition of the legal status of accreditation in healthcare, its weight and its implications on the current functioning of the healthcare sector, are proved by the fact that both the national and the regional legislator have had to intervene many times in the field during recent decades.²⁵

²² On this issue, with specific reference to interactions, see R. Spagnuolo Vigorita, *Politiche pubbliche del servizio sanitario. Profili giuridici*, Napoli, 2003.

²³ On providers' qualification and on their legal nature, N. Aicardi, *I soggetti erogatori delle prestazioni sanitarie*, in *Dir. amm.*, 1998, p. 497 ff.; C. E. Gallo, *La concorrenza nell'erogazione dei servizi sanitari e la posizione delle imprese private*, in *Sanità pubbl. e priv.*, 2003, p. 249 ff.; F. Liguori, *Impresa privata e sociale nella sanità riformata*, Napoli, 1996.

²⁴ On the issue, *ex multis*, Cons. St., V, May 11, 2010, n. 2828.

²⁵ See, for instance, r.l. Puglia, February 1, 2013, n. 3, *Modifica e integrazione dell'articolo 27 della legge regionale 28 maggio 2004, n. 8 (Disciplina in materia di autorizzazione alla realizzazione e all'esercizio, all'accreditamento istituzionale e accordi contrattuali delle strutture sanitarie e socio-sanitarie pubbliche e*

4. National regime for accreditation and its implementation by the regions

Because of the concurrent legislative competences on the issue, regional accreditation systems may differ, provided that they are coherent with the basic standards set at the national level.

First, each regional system may set its own requirements and define its own administrative procedures. As far as this aspect is concerned, regions are expressly required to set their own accreditation requirements both from a substantive and from a procedural point of view. Thus, a presidential decree dated January 14, 1997, indicated minimum common standards, while it is up to the regional legislator to set out other requirements from an infrastructural, technological, and organizational perspective. Procedures for grants, revocations and audits must also be determined.

An analysis of the different solutions adopted at the regional level, as well as at the enforcement stage, may well highlight different trends in the nature of the accreditation regime,²⁶ especially as concerns the position of providers in relation to financial budgetary constraints.²⁷ The output is influenced by many factors, such as historical, economic and political aspects, as well as the form of governance set in each regional environment.²⁸

private), rubricato "Sospensione e revoca dell'accreditamento", which states that «in caso di mancata stipula degli accordi di cui all'articolo 8-quinquies del decreto legislativo, l'accreditamento è sospeso fino alla stipula dei predetti accordi».

²⁶ On the regional healthcare system set out in Lombardia see, P. Previtali Pietro, A. Santuari, A. Venturi, *Il nuovo accreditamento delle unità d'offerta socio-sanitarie in regione Lombardia: profili giuridico-organizzativi*, in *Sanità Pubblica e Privata*, 2012, 5, p. 48 ff.

²⁷ M. Lottini, *Il concorso dei privati al servizio sanitario nazionale: alternativi al pubblico o succedanei al pubblico?*, in *Foro amm. Tar*, 2008, p. 2553 ff. On this issue, G. Corso, *Pubblico e privato nel sistema sanitario*, in G. Corso, P. Magistrelli (eds.), *Il diritto alla salute tra istituzioni e società civile*, Torino, 2009, p. 17 ff.

Secondly, the output may differ greatly, depending on the stage of enforcement as well as on the choices about the transitional regime from the previous conventions.²⁹ In this regard, the full implementation of the accreditation system that was set out at the end of the 1990s met serious difficulties. Its enforcement was delayed several times.³⁰ A strong attempt to bring the process to a conclusion was made in 2006, by the law of December 27, 2006 n. 296 (the so-called *legge finanziaria* 2007), which required the immediate transition from the provisional, transitional accreditation to the definitive one.³¹ Notwithstanding the legal provision, the practical transition took much more time: abandoning the old conventional system for the new accreditation regime proved to be complex and to require many intermediate steps, ruled by continual acts of prorogation adopted by the legislator.

²⁸ See V. Mapelli, *I sistemi di governance dei servizi sanitari regionali*, Quaderni Formez, n. 57, Roma, 2007. On this issue see also E. Catelani, G. Cerrina Feroni, M. C. Grisolia (eds.), *Diritto alla salute tra uniformità e differenziazione. Modelli di organizzazione sanitaria a confronto*, Torino, 2011; S. Antoniazzi, *Governance territoriali e nuovi modelli di organizzazione sanitaria*, in P. Bilancia (a cura di), *Modelli innovativi di governance territoriale. Profili teorici ed applicativi*, Milano, 2011, p. 273 ff. On regional healthcare systems, see Agenas, *Ricognizione sui piani sanitari e sociosanitari regionali vigenti. Anno 2013*, Roma 2014, pubblicato al seguente link: http://www.agenas.it/images/agenas/oss/psr/LetturaRagionata_Psr_vigenti05_06_14.pdf.

²⁹ See Constitutional Court, December 11-19, 2012, n. 292, and Constitutional Court, November 28, 2012, n. 262.

³⁰ See Agreement, December 20, 2012, which defines accreditation as «un processo di valutazione sistematico e periodico svolto da un “organismo esterno” con l’obiettivo di verificare l’adesione a predeterminati requisiti correlati alla qualità dell’assistenza. Tale sistema incentiva l’autovalutazione e il miglioramento, basato su criteri periodicamente aggiornati e verificato da valutatori appositamente formati», nonché afferma che il «miglioramento della qualità è considerato un processo continuo attraverso il quale gli aspetti importanti dell’assistenza sono monitorati e migliorati se necessario e le innovazioni selezionate continuamente».

³¹ On implementation, see Agenas, *Indagine sullo stato di implementazione del percorso di accreditamento delle strutture sanitarie e sociosanitarie private (ai sensi dell’art. 1, comma 796, legge n. 296/2006 e s.m.i.) - seconda indagine*, Roma, July 30, 2010.

4.1. In search of common standards: the Italian national accreditation scheme

To implement what had been stated in the so-called *Patto per la Salute* 2010-2012 (art.7)³², the Ministry of Health commissioned a working group with the task of focusing on the issue of the reform of the legislative framework on accreditation (the so-called *Tavolo di lavoro per la revisione della normativa sull'accreditamento* hereinafter Trac)³³.

Guidelines approved by the working group have been adopted as a national scheme, by an agreement signed on December 20, 2012 within the *Conferenza permanente per i rapporti tra lo Stato, le regioni e le province autonome*.³⁴

The requirements in the agreement are now considered to be minimum standards for institutional accreditation. They have to be complied with by all the regional accreditation systems, and they must be taken into consideration in any regional regulation. Therefore, regions whose accreditation system differs from the general framework set out in the agreement must modify their regulations in order to make them coherent. Many regions have already started moving in this direction.³⁵

³² For first data on the issue, in Agenas, *Fattori/criteri di qualità delle organizzazioni sanitarie da condividere nei sistemi di autorizzazione/accreditamento delle Regioni e da adottare a livello nazionale, come elementi di garanzia del sistema delle cure*, Roma, febbraio 2011, at the following url: http://www.agenas.it/agenas_pdf/Documento%20Fattori_Criteri.pdf.

³³ See Agenas, *Fattori/criteri di qualità delle organizzazioni sanitarie da condividere nei sistemi di autorizzazione/accreditamento delle Regioni e da adottare a livello nazionale, come elementi di garanzia del sistema delle cure*, cit., p. 6. Lgs.D. n. 229/1999 sets a Commission on accreditation and quality in healthcare (*Commissione per l'accREDITamento e la qualità dei servizi sanitari*) with the task to set common standards, to monitor and assess implementation by the regions.

³⁴ See *Allegato A*, Agreement, December 20, 2012, quoted, §1.

³⁵ See the following act, which gives implementation to the agreement: r.b.r. Valle d'Aosta, May 31, 2013, n. 965, *Recepimento dell'intesa sancita il 20 dicembre 2012 tra il Governo, le Regioni e le Province Autonome, sul*

In the meantime, a second working group has been set by the Ministry of Health with the tasks of facilitating the transition to the new scheme, giving support to the implementation of the scheme over the whole nation, and helping the regions to interpret the new standards in a uniform way.³⁶

Specific emphasis is paid in the agreement to the fact that accrediting bodies must be independent. This requirement is of fundamental importance, particularly within those regional healthcare systems where the distinction between providers, regulators and accreditors is considered relevant.

To this end, the agreement also requires accrediting bodies to determine their own working policies in advance, to declare their institutional relationships explicitly, to set their internal organizational frameworks in advance, to indicate the forms and tools for procedural participation, and to predetermine their administrative procedures for assessing full compliance with the conditions for accreditation over time.³⁷

As far as the common guidelines are concerned, the agreement indicates eight commitments related to standards, and for each of these commitments further requirements and implementing processes are set out.

documento recante "Disciplina per la revisione della normativa dell'accREDITAMENTO" e adesione al Progetto di Ricerca Corrente 2012. Approvazione della relativa bozza di convenzione con l'Agenzia nazionale per i servizi sanitari regionali; r.b.r. Piemonte, 28 giugno 2013, n. 9-6021; r.b.r. Veneto, July 5, 2013, n. 1131; r.b.r. Sardegna, n. 42/42 October 16, 2013; r.b.r. Emilia-Romagna, July 2, 2013, n. 884; r.b.r. Liguria, March 28, 2013, n. 371; r.b.r. Friuli Venezia Giulia, July 19, 2013, n. 1703.

³⁶ See Ministerial Decree (hereinafter m.d.) Salute, February 6, 2013.

³⁷ See, for instance, r.b.r. Valle d'Aosta, February 7, 2014, n. 123, *Approvazione dei criteri di programmazione delle verifiche di vigilanza presso le strutture sanitarie, socio-sanitarie, socio-assistenziali e socio-educative site sul territorio regionale, ai fini del mantenimento dell'autorizzazione all'esercizio dell'attività e del relativo accREDITAMENTO, ai sensi della Delib.G.R. n. 52/2010, della Delib.G.R. n. 2541/2012 e della Delib.G.R. n. 1362/2013.*

The first indicator concerns the review of the management and structural organization of the provider. These have to promote good quality in healthcare assistance; the assessment depends on the specific kind of medical centre, whether this is a hospital, a critical access hospital, a laboratory or another type of provider.

As a second indicator, the provision of care, treatment and services is taken into consideration: as far as these factors are concerned, the agreement requires there to be a clear indication of standards for service delivery, criteria for patients' eligibility, strategies for continuing assistance, audit procedures, and monitoring and assessment procedures.

The third relevant factor is related to the quality of infrastructural and structural resources. This has to be reviewed in relation to the use of the resources, and must be considered in the light of the punctual compliance with maintenance rules for medical equipment and with lifesaving arrangements.

Fourthly, the expertise of medical staff is taken into consideration; training and education are considered and are strictly controlled.

A fifth commitment concerns transparency, information management and information policies. To assess whether this factor is being implemented correctly, good practices are: publicity about healthcare protocols being made available to all stakeholders, processes that favour the proactive participation of stakeholders, indicators for internal communication as well as for the assessment of stakeholder satisfaction, information being given to the public about healthcare delivery, patient involvement and information about medical protocols, patient flow and admissions to the service.

To ensure the sixth commitment to safety, which concerns clinical appropriateness, is met, evidence based approaches are required, and also the development of clear protocols on risk management.

Since accreditation is a process, the seventh commitment refers to the management of innovation through processes and to planning technical, professional and management innovation.

Lastly, attention is paid to the condition of each patient through processes aimed at humanizing care, through the evaluation of the whole human being during the overall process of healthcare delivery, and through the care environment.

4.2. The current state of regional differentiation

Later we analyse regional accreditation systems as they developed from the regional experiences in place before the adoption of the national scheme. The analysis is carried out through meaningful examples, since the aim and the scope of this contribution do not allow us to undertake a complete examination of the regional legislation on the issue.³⁸

Common trends, as far as the distribution of competences is concerned, may also be found in regional accreditation systems that existed prior to the intervention for common standards that started in 2010. Regional accreditation systems usually set common standards as well as standards with differentiation for the categories of treatments delivered.³⁹ Three main groups of standards are commonly addressed: organizational standards, protocols on clinical pathways and indicators on patient care.⁴⁰ More attention is

³⁸ Also the guidelines issued by Trac address a series of examples: see v. *Allegato A*, Agreement December 20, 2012, quoted.

³⁹ See: r.b.r. Piemonte, September 14, 2009, n. 25-12129; r.l. Puglia, February 25, 2010, n. 4, *Norme urgenti in materia di sanità e servizi sociali*; r.b.r. Emilia Romagna, 327/04, which enforces r.l. Emilia Romagna, October 12, 1998, n. 34, *Norme in materia di autorizzazione ed accreditamento delle strutture sanitarie pubbliche e private in attuazione del D.P.R. 14 gennaio 1997, nonché di funzionamento di strutture pubbliche e private che svolgono attività socio-sanitaria e socio-assistenziale*.

⁴⁰ See r.b.r. Abruzzo, July, 1 2008, n. 591/P, and r.b.r. Basilicata, December 30, 2012, n. 2753. See also Regional Executive Board Presidential Decree, Toscana, March 3, 2010, n. 29/R *Regolamento di attuazione della R.L. 28 dicembre 2009, n. 82 (Accreditamento delle strutture e dei servizi alla persona del sistema sociale integrato)*;

usually given to commitments related to clinical pathways, while the requirements for organizational management and patient care are less detailed.⁴¹

Organizational and management requirements mainly concern a provider's internal organization, with specific reference to departmental divisions, staff management, or patients' committees. Reference is also made to the quality of the staff and to facilities, as well as to infrastructure, and the requirements here are mainly differentiated by the areas of treatment for which accreditation is requested.

As far as patients are concerned, the main commitment shared by regional accreditation systems is the adoption of patients' charters of rights.⁴² Some systems set detailed requirements related to patients' committees, patients' treatment, users in general, family members and carers and their participation in decision making, and complaints management and dispute resolution.⁴³ The Sardinian accreditation system, for instance, makes reference to periodical consultations through the circulation of questionnaires among patients and users in general.⁴⁴

Regional Executive Board Presidential Decree, Toscana, January 8, 2014, n. 1/R, *Modifiche al decreto del Presidente della Giunta regionale 24 dicembre 2010, n. 61/R (Regolamento di attuazione della legge regionale 5 agosto 2009, n. 51) in materia di autorizzazione e accreditamento delle strutture sanitarie.*

⁴¹ See r.b.r. Basilicata, n. 2753/2005.

⁴² Participation and information are considered main aims by the regional healthcare planning Act adopted by Veneto: PSSR 2007-2009.

⁴³ See r.l. Abruzzo, March 10, 2008, *Un sistema di garanzia per la salute – Piano sanitario regionale 2008-2010, (allegato 2.2.)*; See *Programma Operativo 2013-2015*, approved by commissarial decree October 9, 2013, n. 84, as integrated and amended by Commissarial Decree, December 30, 2013, n. 112.

⁴⁴ See r.l. Sardegna, November 7, 2012, n. 21, *Disposizioni urgenti in materia sanitaria connesse alla manovra finanziaria e modifica di disposizioni legislative sulla sanità.*

A strong role in the assessment of regional accreditation systems is played by the conditions for the suspension, revocation or denial of accreditation. There are many reasons for the adoption of these adverse acts: for instance, accreditation may be revoked when a provider's standards become inconsistent with quality requirements,⁴⁵ or when a provider's activity proves not to be coherent with regional healthcare planning,⁴⁶ or when a healthcare provider does not comply with the conditions included in a contractual agreement.⁴⁷

Two of the main reasons for revocation are the suspension of the former authorization and the overspending on the annual budget assigned to the contractual agreement. Other minor forms of violations that may lead to revocation may be related to standards concerning the management of human resources.⁴⁸

Regional accreditation systems may also differ from another point of view, that of codification: the regional legislator may choose to gather together the conditions and procedures for accreditation in a manual,⁴⁹ or in distinct manuals,⁵⁰ or may set them forth in

⁴⁵ See art. 27, paragraph 6, r.l. Puglia, May 28, 2004, n. 8, *Disciplina in materia di autorizzazione alla realizzazione e all'esercizio, all'accreditamento istituzionale e accordi contrattuali delle strutture sanitarie e socio-sanitarie pubbliche e private*.

⁴⁶ See art. 21(e), r.l. Puglia, n. 8/2004.

⁴⁷ See r.l. Emilia Romagna, February 19, 2008, n. 4, *Disciplina degli accertamenti della disabilità - ulteriori misure di semplificazione ed altre disposizioni in materia sanitaria e sociale*.

⁴⁸ See art. 7, paragraph 5, r.l. Abruzzo n. 32/2007.

⁴⁹ See, Marche, *Sistema e requisiti per l'accreditamento delle attività sanitarie da parte delle strutture pubbliche e private della regione Marche (ai sensi della legge regionale n. 20/2000)*; *Manuale di Accreditamento*; Liguria, *Manuale per l'accreditamento delle strutture socio-sanitarie pubbliche e private*, April 2, 2002; r.b.r. Calabria, March 9, 2009, n. 61, *Regolamenti e manuali riguardanti i requisiti di qualità, strutturali, tecnologici ed organizzativi per l'Autorizzazione e l'Accreditamento delle strutture sanitarie e socio-sanitarie pubbliche e private ai sensi del comma 5 art. 11 legge regionale 18 luglio 2008, n. 24*.

different acts of different natures.⁵¹ Collecting all the rules about standards and procedures into one act serves to guarantee legal certainty and transparency, favouring easy interpretation by users.

Different solutions are also adopted as far as the allocation of competences is concerned. In most regional systems, the regional health department or the regional board⁵² is vested with accreditation tasks. If this is the case, these regional bodies bring together both the political and the administrative functions on accreditation. The disadvantage is that, preferably, these tasks should be kept distinct in the Italian healthcare sector, where political influence has been predominant for a long time. Conflicts of interest may also arise when local health units (*aziende sanitarie locali*) are vested with accreditation functions: in this case these public entities act as both regulators and providers. Moreover, of course, the allocation of powers on accreditation may look less controversial in those regional systems in which local units do not act as providers but are vested only with regulatory functions, as in Lombardia, for instance. As a reaction to the practice in Campania, which delegated to the local health units competences related to the accreditation process, for instance, we may note the prompt intervention by the *commissario ad acta*, which prohibited these local units from granting new accreditations⁵³ and subsequently vested the regional administration with decisional powers related to

⁵⁰ See r.b.r. Abruzzo, n. 591/P/2008, on *Approvazione manuali di autorizzazione ed accreditamento, nonché delle relative procedure delle strutture sanitarie e socio-sanitarie*, and the subsequent amendments resolution June 1, 2009, n. 36/09, Regional Decree (hereinafter r.d.) December 2, 2011, n. 61, r.d. October 7, 2013, n. 73.

⁵¹ See r.b.r. Basilicata, n. 2753/2005, *Manuale dell'accREDITAMENTO delle strutture pubbliche e private*, and r.b.r. Basilicata, October 13, 2006, n. 1958, which sets out the administrative procedure for accreditation.

⁵² See art. 6, r.l. Abruzzo, n. 32/2007.

⁵³ See the Decree issued by the *Commissario ad acta*, Campania, December 30, 2009, n. 21, *Divieto delle Aziende sanitarie di procedere a nuovi accreditamenti per l'anno 2010*.

accreditation, leaving only the instruction phase to separate commissions that are part of the local units.⁵⁴

Independently of the basic choice regarding who is competent, in almost all of the regional systems a distinction is made between the instruction phase and the decision phase of the proceedings. In most cases technical commissions or expert committees are vested with the responsibility of the instruction phase. Solutions may vary widely and the result is not always clear. These bodies may be more or less independent of the regional administration itself, or they may be shaped as regional agencies that are linked in some way with the regional administration. Solutions may vary not only in substance, but also from a formal point of view: observers, groups of experts, committees and agencies are only some examples of the expressions used to define these bodies. In itself, the choice of allowing a separate body to intervene in the first phase of the proceedings proves that there is an attempt to neutralize political influence. In order to define the legal status of, such bodies, their membership and any possible links that they have with bodies vested with decisional powers, or with regulatory bodies, or with providers, must be investigated. As far as membership is concerned, some systems require the participation of a representative of a particular professional category or of a group of patients;⁵⁵ other systems may ask

⁵⁴ See the Decree issued by the *Commissario ad acta*, Campania, March 22, 2011, n. 22; r.l. Campania, December 14, 2011, n. 23.

⁵⁵ See for instance the example of the Abruzzo regional system, where a Group of regional experts was set within the Committee on regional coordination for accreditation (respectively *Gruppo di esperti regionali per l'accreditamento* – Gera, *Organismo regionale per l'accreditamento* – Ora, and *Comitato di coordinamento regionale per l'accreditamento* (so called. Ccra). As established by r.l. n. 5/2008, *Allegato 2.3.*, § 2.1., Gera members are professionals appointed by regional health units, healthcare providers' associations, associations of chartered professionals, associations representing patients.

external and independent experts to take part;⁵⁶ and others may include independent professionals chosen from a regional list of experts.⁵⁷

Connections with regional administrations or with the regional health units may be strong, as they are when officers from the regional organizational framework are called upon to take part: this is what happens with the Calabrian accreditation system, where the committee is formed from independent experts but is set within the organizational framework of the regional administration.⁵⁸ In other cases, the connections look weaker, as, for example, when instructor tasks are assigned to agencies as instrumental bodies set within the regional administration.⁵⁹

⁵⁶ See r.l. Emilia Romagna, February 19, 2008, n. 4, *Disciplina degli accertamenti della disabilità - ulteriori misure di semplificazione ed altre disposizioni in materia sanitaria e sociale*; r.b.r. Liguria, July 9, 2007, n. 767, *Commissione Tecnica per la verifica dei requisiti di accreditamento" - Integrazione membri esperti*.

⁵⁷ See r.b.r. Campania, September 22, 2006, n. 1489; Managerial Resolution Molise, July 24, 2009, n. 2, *R.L. 18/08. DGR 244/09. Codice deontologico dei Valutatori per l'Accreditamento Istituzionale della Regione Molise. Provvedimenti*; r.b.r. Toscana, January 11, 2011, n. 12, *R.L. 51/2009: modalità di accesso all'elenco regionale dei valutatori e requisiti richiesti*, r.b.r. Umbria, May 16, 2002, n. 612, on *Progetto ministeriale: "Collaborazione interregionale per lo sviluppo ed il mantenimento competenze qualificate per le verifiche di accreditamento" Convenzione Regione Emilia Romagna e Regione Umbria*, and Managerial Resolution Umbria, January 11, 2012, n. 86, *Istituzione, approvazione e pubblicazione dell'Elenco Regionale dei Valutatori e degli Esperti Tecnici per svolgere l'attività di Audit per l'Accreditamento Istituzionale delle strutture sanitarie e socio-sanitarie della Regione Umbria*.

⁵⁸ See art. 1, r.b.r. Calabria, June 17, 2011, n. 255, *Regolamento per l'organizzazione e il funzionamento delle Commissioni aziendali per l'autorizzazione e l'accredimento*, and, previously, art. 12, r.l. Calabria, July 18, 2008, n. 24.

⁵⁹ Art. 13, l.r. Lazio, March 3, 2003, n. 4, allocates tasks between the Regional Executive Board and the Regional Health Unit. The former «stabilisce, con apposito provvedimento, sentita la competente commissione consiliare, i requisiti ulteriori di qualificazione per il rilascio dell'accredimento nonché gli indicatori ed i livelli di accettabilità dei relativi valori per la verifica dell'attività svolta e dei risultati raggiunti in relazione alle prestazioni

The allocation of competences has a specific relevance to the relationships between choices on accreditation and regional planning for the annual budget, especially under conditions of progressive expenditure constraints. Both financial decisions and planning ones may limit subsequent decisions on accreditation.⁶⁰ Again, differentiation may be found within the regional system, which is an expression of the historical, political and also economic situation of the Italian regions. Some systems, such the one in force in Emilia Romagna, rely particularly on planning.⁶¹ In some other cases the limitations coming from planning seem to be stronger with reference to the accreditation of private providers.⁶² In yet other cases, standards for selection among providers when there are financial constraints become almost arbitrary. This is what has been affirmed by the Italian Constitutional Court with reference to the legislation approved in Campania, where the regional legislator decided that when the number of accreditation requests exceeded the regional need, the selection should mainly take into account the chronological order of the submission of requests.⁶³

accreditate». A regional regulation, sets procedures for asking and obtaining accreditation: also in this case the instruction phase of the proceeding rests on the Public Health Agency (*Agenzia di sanità pubblica*).

⁶⁰ With a focus on healthcare planning, see Cons. st., *Ad. Plen.*, April 12, 2012, n. 3-4.

⁶¹ See r.b.r. Emilia Romagna, February 23, 2004, n. 327.

⁶² See, for instance, art. 21(e), r.l. Puglia, May 28, 2004, n. 8.

⁶³ See Const. Court, n. 292/2012.

5. TIMING IN ACCREDITATION SYSTEM: PROVISIONAL, TRANSITIONAL AND DEFINITIVE ACCREDITATION

On the one side, differentiation in the output of the accreditation system is a reasonable consequence of the choice to allocate main competences in healthcare at the regional level. This constitutional choice has from the beginning been effective in preserving divergences in regional health systems and the original features of different regions. On the other side, differences in the implementation stage, which translate into delays in enforcement, may not seem so acceptable.

Unfortunately, most regional systems (if not quite all of them) experienced serious delays in implementing the accreditation regime. In part, these delays are rooted in the conditions found within each regional environment. From this point of view, many factors were at work at the regional level that impeded a prompt implementation of the regime that was in place after 1999. Emerging and sometimes unexpected practical obstacles, forms of administrative reaction and political pressures played major roles, slowing down progress toward the full establishment of the new system.

In part, accreditation itself, as a process, necessarily requires time before it can enter into force. Assessment against standards itself requires a process that must be developed not only through an *ex ante* examination, based on the *status quo* as well as on forecasts, but also through an *ex post* examination, based on the output of the process.⁶⁴ Furthermore, accreditation also requires an impetus to be given to new and continuous improvement actions.

⁶⁴ See M. Consito, *quoted*, p. 43. See r.b.r. Emilia-Romagna, January 21, 2013, n. 53, *Indicazioni operative per la gestione dei rapporti con le strutture sanitarie in materia di accreditamento*.

Moving on from the difficulties met by the regions in implementing accreditation, the national legislator intervened several times, with multiple prorogation acts, extending the deadline set for the provisional or transitional regime and that for exceptional regimes.⁶⁵

The agreement on healthcare, or the so-called *Patto per la Salute*,⁶⁶ which was signed in 2006, initially indicated January 2008 as a deadline for the termination of the transitional regime regarding health providers authorized under the previous regime.⁶⁷ Later, the deadline was postponed to December 2010. The same deadline set for provisional accreditation has been postponed several times. The initial deadline of January 2010⁶⁸ has been postponed to January 2011,⁶⁹ and to January 2013.⁷⁰ Similar prorogation acts have been approved by regional legislators.

Moreover, different forms of accreditation had to be applied, depending on the status of the providers. The new regime had to be applied differently to different providers because of the fact that many providers had been operating for a long time within the previous regime, while others wished to have access for the first time. For both these

⁶⁵ On this issue, see Constitutional Court, November 19, 2012, n. 260. Under a critical perspective, even if specifically related to the University system, on bureaucratization and over-regulation provoked by accreditation procedures, G. Vesperini, *Iperregolazione e burocratizzazione del sistema universitario*, in *Riv. trim. dir. pubbl.*, 2013, p. 947 ff.

⁶⁶ See *Protocollo di intesa tra il Governo, le Regioni e le Province autonome di Trento e di Bolzano*, adottato in data 28 settembre 2006. The deadline has been reaffirmed by l. December 2, 2006, n. 296, so called *legge finanziaria 2007*: see, art. 1, paragraph 796 (u); (t).

⁶⁷ According to art. 6, paragraph 6, l. December 23, 1994, n. 724.

⁶⁸ See art. 7, *Patto per la salute 2009*, December 3, 2009.

⁶⁹ See art. 2, paragraph 100, December 23, 2009, n. 191 (*legge finanziaria 2010*).

⁷⁰ Paragraph 35, art. 2, Law decree December 29, 2010, n. 225, l. February 26, 2011, n. 10.

groups of providers an experimental period had to be set, since the procedural nature of accreditation does not allow recognition to be granted immediately. Thus accreditation has tried out different qualifications: provisional accreditation for new entrants, transitional accreditation for incumbents, and definitive accreditation for a few providers and a few regional systems.⁷¹

Meanwhile, some solutions have been put under the scrutiny of the Constitutional Court.⁷²

Further delays have been experienced by those regions that have been put under governmental control because of financial constraints (subject to the so-called *piani di rientro*). In these situations, the interactions between accreditation, healthcare planning and the reduction of public funds have rendered the enforcement of the accreditation process even more difficult. Data circulated by the Ministry of Health for the period 2011-2013 confirm a low rate of implementation.⁷³ In this, different forms of non-compliance may be listed. Some regions met the deadlines for completing their accreditation procedures; some

⁷¹ See Cergas-Bocconi, *Osservatorio sulla Sanità Privata in Italia e in Lombardia. Ricerca del CERGAS Bocconi per il Gruppo Merceologico Sanità di Assolombarda*, Milano, March 2, 2009, p. 15, at the following url: http://www.cergas.unibocconi.it/wps/allegatiCTP/Executive%20Summary_osservatorio_2.pdf. According to a research developed by *quotidianosanità.it*, published in January 12, 2011, the 89,8% of providers have been definitively accredited in the North West of Italy; 77,4% in islands; 35,7% in North East; 28,1% in Central Italy; 24,1% in the South of Italy. On this issue, see A. Oneto, M. Marabini, *Dall'accreditamento istituzionale all'accreditamento definitivo*, in *Tendenze nuove*, 2008, p. 123 ff.; A. Oneto, *Dall'accreditamento istituzionale all'accreditamento definitivo?*, in *San. pubbl. e priv.*, 2007, 5, p. 17 ff. See also r.b.r. Emilia Romagna, June 6, 2014, n. 7597, *Approvazione schema di domanda per l'accreditamento socio sanitario definitivo*.

⁷² We refer to art. 2, paragraph 237-*vicies quarter*, r.l. Campania, March 15, 2011, n. 4, which was stated as not coherent with the dictate of art. 117 of the Italian Constitution: see Constitutional court n. 132/2013 and, previously, n. 292/2012.

⁷³ Data are referred to annual meeting 2011: see data published in June 2013, to the following url: http://www.salute.gov.it/portale/news/p3_2_1_1_1.jsp?lingua=italiano&menu=notizie&p=dalministero&id=1151.

did not adopt the necessary resolutions concerning regional needs; some prolonged the transitional phase before definitive accreditation; in some regions there were delays in issuing authorizations as well as in finalizing contractual agreements, and in other regions, such as Campania, the regulations had to be re-drafted, following the rulings by the Constitutional Court; finally, some regions met difficulties in enlisting caregivers potentially interested in obtaining accreditation, and in updating and finalizing the proceedings.

The results described rest on multiple factors; this highlights the importance of the quest for more uniform standards and, therefore, the relevance of the latest interventions in this area. Nevertheless, other major obstacles in the implementation of accreditation are represented by the costs of the process itself, by its administrative management and by the lack of a pre-existing culture concerning the quality of care, which made the process of mapping regional needs, reshaping public caregivers and developing accreditation processes complex.

6. CONCLUDING REMARKS

Some concluding remarks emerge from the analysis that has been performed so far.

First, in implementing accreditation, regions have made use of their autonomy to work with their own attitudes, administrative conditions and political needs. The output often controversial.

Secondly, the process of accreditation itself has proved to be complex. What is interesting to notice is that implementation has proved to be complex not only at the regional level but also at the national level. The regulatory framework is itself complex: many subsequent acts have been approved, difficulties in interpretation and coordination have been raised, and the continual substitution of precedent acts with new decisions has been experienced. Interpretative guidelines have emerged as a necessity, and a need for

clarifying acts that specify procedures, criteria and other related aspects has arisen. Uniformity has become more and more important. Best practice has been seen in those regions that brought together the requirements into one coordinated act (a so-called *Testo unico*), in an effort to achieve transparency and legal certainty. If to some extent this output matches the process-based features of the accreditation system, which requires continuous checks and updates, nevertheless the failure to reach definitive accreditation in most of the Italian regions must be taken into adequate consideration. In this regard, the latest initiatives in the implementation of an agreement on common standards show that a virtuous cycle is starting.

Lastly, the progressive constraints on public expenditures have exerted a great deal of pressure, and this has mainly been an influence in those regions that have been put under governmental financial control. Nevertheless, financial pressures and limits have also played a role in other regions, by connecting the accreditation system to acts for the planning of healthcare, putting under serious threat the basic and express principles of our healthcare system such as the public and private mix in healthcare provision that is aimed at ensuring that patients have freedom of choice.⁷⁴

⁷⁴ On this issue, see Constitutional Court, November 20, 2000, n. 509.