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Legal value of clinical competence and its certification

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ABSTRACT

What is the legal value of the assessment and certification of professional skills and competence? The certification of skills can be defined as a process by which a third party gives written assurance that a person satisfies all requirements needed to operate to the highest professional standards in a specific field. Today, the certification of skill scan have a legal value in the context of professional responsibility when a judge has to assess the degree of expertise of a doctor who is under investigation for malpractice. From a legal point of view, it has some value regarding credits for professional appointments or career development within the state system. It is desirable that more and more both national and regional legislation should use the system of certification of skills through accredited third-parties to improve and assess the performance of professionals and the institutions and structures in which they operate. The system of certification of skills has to become part of the requirements for the accreditation of public and private facilities that provide services to the national health service. We believe that the certification of skills not only helps to recognize human intellectual capital, which is the main value of a healthcare organization, but also facilitates decisions about career paths and the construction of an effective training and study curriculum and portfolio.

Introduction

This paper aims to examine the legal value of the evaluation of professional competence. This is of concern to those professionals who have been involved in the methodology and clinical aspects[1] of models of evaluation of clinical competence. Before analyzing the problems involved, it is useful to take a look at the concept of clinical competence itself. This has a much wider scope than the most commonly used models evaluating the technical ability of health care professionals.

Clinical competence can be defined as the physician's ability to evaluate and manage the patient's problems through the use of the best methodology, knowledge, technology and support available from other personnel in order to promote patient good health and satisfaction.[2] All this must take into account the different abilities of the individuals involved and the context in which they operate, such as the physician in charge, the institutional structure and clinical organization, the patient's family, health care staff, etc. It is in consideration of these elements that *clinical competence* broadens the scope of professional ability. It is not, therefore, just a list of the health care professional's technical abilities, but unifies professional, managerial and social qualities with the operative ability of the specialist. Once we have clarified (as far as is possible) the concept of clinical competence, we need to look at how far this ability can be certified and, therefore, assume legal value. In general, certification of competence can be defined as a procedure through which a third-party provides a written guarantee that the person involved satisfies all the requirements needed to operate to the highest professional standards in a specific field. Given this, what legal value can the evaluation and certification of professional skills have? To find an answer, we need to look at each issue in turn: i) the evaluation and certification of professional competence must be governed by the law? ii) what legal value does certification of professional competence have in giving access to the medical profession? iii) are there regulations currently in force within the medical profession that stipulate the need for an evaluation of competence? iv) what impact does certification of professional competence have on professional responsibility?

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The evaluation and certification of professional competence must be governed by the law?

The question of competence starts to become not just a professional duty,[3] but also a legal fulfillment of health care services and assistance, in particular for those health care institutions and structures that must satisfy specific

requirements in order to be authorized to operate on behalf of the national health service. Some Italian regional authorities (Emilia Romagna, Tuscany, Calabria) have already stipulated under the term *clinical competence* the need for the health institutions and structures to document all the re-fresher and training courses that medical and nursing staff do. This guarantees that individual competence is developed and maintained according to a training program that takes into consideration the criteria and requirements of the Continuing Medical Education (CME) program.[4-11] Fulfillment of these requirements is a necessary condition to maintain the accreditation that is the legal prerequisite to allow institutions and professionals to operate on behalf of the regional health service. It is also clear that the concept of clinical competence is much wider than that covered by regional regulations. However, from a legal point of view, it is in any case important to underline that this concept starts to gain importance for the regional legislator when it has to decide whether or not to confirm accreditation to a health organization or whether the accreditation should be maintained. It is also obvious that, in the future, the competent regional legislators responsible for the accreditation must change their approach, and not limit themselves to only evaluating the procedures and structural resources available, but must also evaluate the competence of the professional staff who work there, in order to guarantee that the quality of service provided is continuously improved. In fact, it seems evident that in cases in which the organizational structures and strategies are similar, the real difference is made by the professional staff themselves. Certification of professional competence offers, therefore, a readily available and continuous guarantee of standards. Besides providing a clear professional profile, certification of professional competence is both a sign of efficiency and competitiveness, and a means of promoting efficient system management and transparency. Without a doubt, one of the problems posed by such future changes is the question as to who can certify competency. This could be carried out by the organization or institution itself (or other accredited bodies) on the basis of the models of evaluation of clinical competence of the medical specialist as defined by the recognized national scientific society or by government bodies, *e.g.* the Ministry for Health and Research.

What legal value does certification of professional competence have in giving access to the medical profession?

As we have already seen, certification of competence can be given by a third-party even within the institution in which the professional works itself or by an independent specialized scientific society. This, after due examination, can recognize and certify whether an individual subject satisfies competency requirements. In contrast to a simple *recognition* of competency, the certification is also a way of informing others of the competence accredited. It is known that, for some time now, the legal value of professional qualifications has been a subject of much debate[12] and is sometimes attributed with moral obbligations that have still not been well defined. The current Italian judicial position is one that recognizes professional qualifications that are obtained through true and proper public certification by authorized bodies (*e.g.* universities) as part of the exercising of a public authority and *in the name of the Law*. Such judicial recognition also carries *legal protection*[13] while holding such qualifications represents the necessary conditions for admission to state examinations that need to be passed in order for subjects to enrol in professional registers and orders and to apply for jobs in the public health sector. In fact, the need to have certain precise qualifications in order to be able to apply for some jobs is set out in European Union law and, in particular, in the European Commission Decision of 7 September 2005 (no. 2005/36/CE)[14] concerning the recognition of professional qualifications and the relevant internal provisions made (Italian Legislative Decree no. 206, 9/11/2007).[15]

In consideration of the possibility of physicians using their certification of competence to access jobs in the public health sector, the main regulations of reference are the Italian Legislative Decrees no. 483 (of 10/12/97),[16] and 484 (of 10/12/97).[17] The tables showing the equivalent disciplines and specializations refer to the Italian Ministerial Decrees of 30/1/98[18] and 31/1/98[19] as well as that of the Italian Legislative Decree no. 254.[20] An analysis of these shows that certification of competence can only assume legal value in the overall evaluation of the curriculum made by the competent bodies of the candidate's professional activities, studies and training, all officially documentated, that do not refer to qualifications already evaluated in previous categories. Such qualifications give further evidence of the level of professional training acquired throughout an individual's entire career with specific reference to the position applied for.[16] Altogether, from this we can conclude that, for the moment, no real *legal value* has been attributed to the certification of competence as a vehicle of access to the medical profession. Certainly, it can have a *training value* and an *added value* that should be considered in the overall evaluation of the individual. In fact, we know that various ways of giving value to such certifications are being studied and the basic conditions are being laid down to make sure their application is useful.

Are there regulations currently in force in the medical profession that stipulate the need for an evaluation of competence?

It is important to note that evaluation of competency is also part of the system of evaluation of health care pro-

fessionals who have a managerial role. It is first of all useful to remember that the physician-manager must, besides evaluation of the individual *performance*, have both an *active* and a *passive* role. In other words, these physician-managers both evaluate others and are in turn evaluated themselves. We will then consider them according to the evaluation of their own competence as established by the 2009 Italian Legislative Decree no. 150[21] concerning criteria for the evaluation of managers. For the moment, the roles that can be given to managers within the public health service who are physicians and veterinary surgeons are: i) manager of large institutions and structures with a regional administrative role; ii) manager of small specialized institutions and departmental structures. These can also be part of a larger institution; iii) positions of specialists, consultants, study investigators and researchers, inspectors; iv) professional positions that can be given to managers with less than 5 years experience.

Currently, the 1992 Italian Legislative Decree no. 502[22] provides for three independent control stages: i) the first, renewable each year, according to results obtained on the basis of the objectives related to the position held and presented to an evaluation body; ii) the second, renewable every three years, on the professional activities carried out and the results obtained by all managers and reviewed by a technical committee; iii) the third, on the expiry of the contract, evaluating whether the contract should be renewed.[23] Recently, agreement was reached on the National Collective Work Contract for Medical Managers (*Contratto Collettivo Nazionale di Lavoro, CCNL*).[24] Results will be checked each year in order to monitor managerial activities. The professional activities carried out should have been the subject of independent checks every three years. Such controls have now unified to form a single control system to confirm the position held (CCNL, art. 25: *La verifica e valutazione dei dirigenti*).[24] The evaluation system currently provides for two fixed controls: one yearly and the other when the contract expires. Furthermore, the professional activities of all newly appointed managers will be evaluated after the first five years.

Evaluation of competence involves all managers and mainly covers two areas: i) differentiated managerial and professional roles; ii) checking that budgetary, personnel and/or individual objectives have been reached. This should take into consideration: i) the internal collaboration and level of multi-professional interaction in the organization of the department; ii) the level to which assigned functions assigned as part of the operative and quality management are carried out; iii) the results of control procedures and with particular regard to the clinical appropriateness and quality of the services given, the counseling and training provided, the individuals who receive services, certification of service quality; iv) the efficacy of the organizational models adopted in order for objectives to be reached; v) the ability shown in motivating, guiding and evaluating staff and of creating a favorable organizational context that promotes optimal use of resources through a balanced recognition of the work load of staff, the services given, and management of institutes under contract; vi) the ability shown in managing and promoting technological and procedural innovations, in particular with regard to respecting time-frames and conditions of budget negotiations in relation to assigned objectives as well as training schemes and staff selection; vii) the ability to promote, make known, manage and implement the guidelines, protocols and diagnostic and therapeutic recommendations to be used; viii) the activities of clinical research and experimentation programs carried out, of training given, of university study commitments and activities within permanent institutional training programs; ix) the attainment of the minimum training credit as set out in article 16(3), subsection 2 of the 1992 Italian Legislative Decree no. 502[22] in consideration of article 23, subsections 4 and 5; x) adherence to the attached code no. 1 of the present contract, taking into account also the way in which managerial responsibility is exercised and of the obligations inherent in the code of ethics (CCNL, art. 28: *Effetti della valutazione positiva delle attività professionali svolte e dei risultati raggiunti*).[24] To this system of evaluation of competence which is mainly derived from contractual arrangements,we must add the new modifications introduced with the 2009 Italian Legislative Decree no. 150,[21] better known as the Brunetta Decree. This constitutes the main tool to be used to evaluate *performance* in the public administration, and deals with such aspects as merit, transparency, awards, managerial responsibility and re-negotiation of contracts. This decree was followed by a series of explicit deliberations arising from the Commission for the Evaluation, Transparency and Integrity of the Public Administration (*Commissione per la Valutazione, la Trasparenza e l'Integrità delle Amministrazioni Pubbliche, CIVIT*). This commission was set up to offer operative support to the application of the law and its monitoring.[25,26] The Decree has established conditions under which, according to article 9, the different institutions must define a system by which to evaluate individual performance connected to: i) performance markers relating to organization of direct responsibility; ii) achieving specific individual objectives; iii) the quality of the contribution guaranteed for the general performance of the institute or structure, and the professional and managerial competencies demonstrated; iv) the ability to evaluate staff, demonstrated through a significant differentiation of judgement.

We can say that recognizing the professional ability of each member of staff is certainly the way in which it becomes possible to design professional development strategies and individual training programs according to the skills necessary for the assigned role. However, evaluation of the professional competencies or the in-

dividual evaluation of each single member of staff requires: i) a clear definition of the means of evaluation of the competencies that can not be the same for the physician as for other managers but should instead bear in mind the specific characteristics of each manager. Therefore, definition of standards of evaluation of competency is essential for a correct evaluation of the medical management; ii) a definition of what will be the repercussions of the system of evaluation of competency on the main institutions involved, such as: i) retribution for the results; ii) assignment of new and subsequent jobs; iii) the managerial responsibility.

What impact does certification of professional competence have on professional responsibility?

The need for a constant update and improvement of competency remains the most important issue for health care professionals and this is already a subject of precise judicial regulations.[22] In terms of professional responsibility, article 2236 of the Civil Code relates to expertise, limiting civil responsibility of the physician for grave offence. This, however, limits the judicial decision to *particularly difficult cases*, such as newly emerged problems that have not yet been sufficiently studied or that are subject to contrasting deliberations and treatment. If such proceedings take place in a civil court it should be said that considering its criminal finality, medical offence is evaluated according to the standards of ordinary criteria as established by article 43 of the Penal Code[27] and not by those established by article 2236 of the Civil Code[28] for which also the trivial offence is emphasized. This is also to be referred to, in terms of collectability, receivability, exigibility, to the objective parameter of *a model of expertise and moral integrity to whom the conduction of that activity is entrusted*, considering, among other things, with regard to how far the error can be excused, of the degree of technical-scientific difficulty of the case.[29] It is clear that the physician must be informed of any new methods and knowledge that reduce the *special difficulty* into *ordinary practice*. The physician can not call upon any personal limitations (which may arise from a lack of such knowledge and not from any objective difficulty in understanding) in order to avoid being considered responsible for any offence. In this sense, the law has expressed that, with regards to the activities of the medical profession, the individual must be considered responsible because of incapacity for any conduct by which a certain intervention, whether or not this is defined in writing, is not performed correctly; this does not concern the inherent risk covered by the regulations related to the choice between therapeutic interventions, but to a further risk in the carrying out of professional duties. In order to evaluate the extent of the risk taken into consideration by the regulations, the forseeableness and the possibility of preventing the risk must be clearly established with due attention to all the circumstances in which the subject operates and on the basis of the level of understanding he or she has achieved.[30,31] In the light of this, we can say that in the case of contentious certification of competence, such certification can be freely evaluated by the Judge and by the Official Technical Consultant in order to identify the level of skill of the health care professional on the basis of standards established by the scientific societies, and to evaluate whether these correspond to those required by the certification process. For example, if from the parameters defined by a Scientific Society[31] it can be concluded that the general professionalism of a physician specialized in Internal Medicine means that he or she is capable of reading an electrocardiogram and recognizing cases of stroke, lesions and necrosis, if those conditions are not recognized by someone who has been certified as competent then this would be defined as incapacity. On the other hand, knowing how to manage thrombolysis in cases in which this procedure is required, according to such pre-established parameters would identify a high level of professional skill. Consequently, in case of error by the physician certified as having basic competence, the error and therefore the judge will evaluate the psychological element of the blame with less severity and will judge in favor of the physician.

In conclusion, we can say that today the certification of competence can have legal value with regard to professional responsibility when a judge has to evaluate the degree of ability of the physician under investigation for malpractice while the principle of the law has only a relative value when it comes to assigning professional appointments or in career development within the public sector. It is to be hoped that the future will see more national and regional legislation using the system of certification of competency through accredited subjects and third-parties[32] to improve and evaluate the performance above all of health care professionals and then of the institutions and structures where they work. It is also to be hoped that the system of certification of competency becomes part of the prerequisites for accreditation of both public and private structures that provide services on behalf of the national health service, since such certification not only identifies that intellectual capital that is the principal value of any health service, but also helps decision-making with regards to careers.

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