NEWS AND VIEWS

Legal Analysis of the Spanish Basic Law 41/2002 on the Autonomy of the Patient and the Rights and Obligations with Regard to Clinical Information and Documentation

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Preliminary remarks

In November 2002 the Spanish Parliament passed Basic Law 41/2002 on the autonomy of the patient and the rights and obligations with regard to clinical information and documentation (the Patients’ Rights Law, hereafter “PRL”). As provided for in Article 1, the purpose of the Law is to regulate the rights and obligations of patients, users and professionals, as well as public health centres and services, with regard to the autonomy of the patient and clinical information and documentation.¹ In other words, the PRL aims to protect such rights and define such obligations in the context of health care interventions.

These rights are already acknowledged in Article 10 of the General Health Law 14/1986 (hereafter, “GHL”),² which lays down a list of patients’ rights before the Health Public Administrations.³ However, that list of rights has proven to be insufficient in the present context, mainly due to a change of attitude towards health care, with an ever growing awareness of such rights in the context of health care relations and a correlative need for defining these rights and their content. This change of attitude has been reflected in several legal instruments both at the international and national level. One of the most significant international instruments is the Convention of the Council of Europe for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (hereafter “CHRB”), signed on 4 April 1997 and which entered into force in Spain on 1 January 2000.

As mentioned in the introductory statement of the PRL, the CHRB is particularly relevant for two reasons. Firstly, it lays down a common framework for the
protection of the rights of patients in biology and medicine. Secondly, it is the first international legal instrument in this field that is binding on the signatory parties. The CHRB acknowledges rights such as privacy, the right to information and informed consent, among others. The ratification of the CHRB by Spain provoked the need for a reform of the existing legislation on health care because, on the one hand, many aspects of the GHL were in contradiction with the CHRB, and on the other, some of the new rights provided for in the latter were not yet acknowledged in any legal provision.

At national level, as a result of the evolution of the patients’ rights and of the insufficiency of State legislation in this regard, several Autonomous Communities had already started to pass laws in areas such as that of clinical records, informed consent and prior instructions. This situation has provoked a clear violation of the right to equal treatment laid down in the Constitution because these rights are guaranteed only for some citizens, which has made necessary to establish guidelines for their obligatory application throughout the Spanish territory. Similarly, the coexistence of Autonomic and State legislation such as Organic Law 15/1999 of 13 December 1999 on personal data protection highlights the disperse and heterogeneous nature of health care legislation, a situation that the PRL now tries to resolve.

In conclusion, the PRL addresses the need to (i) comply with the provisions of the CHRB and to reform the GHL accordingly, (ii) establish basic provisions applicable throughout the Spanish territory as regards the rights of the patients so that all citizens enjoy the same guarantees and (iii) treat these issues in an uniform and integrated manner, avoiding diverging regulations. We analyse below in greater detail the main changes and also the main innovations introduced by the PRL.

**The right to information**

Chapter 2 of the PRL states the right to health information. Article 4.1 regarding health care information, provides that “Patients have the right, by virtue of any intervention in the scope of their health, to know any information available on their health, with the exceptions provided for in the law. Moreover, any person’s will not to be informed shall be respected. Such information shall include at least the purpose and nature of each intervention, its risks and consequences, and, as a general rule, shall be provided verbally with a note being made in the clinical record”. Article 6, with respect to epidemiological information further establishes that “Citizens have a right to know the health problems of the community when they imply a risk for public health or for their own individual health, and the right