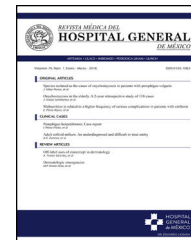




# REVISTA MÉDICA DEL HOSPITAL GENERAL DE MÉXICO

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## EDITORIAL

### Mexican official norms: Concept, background and legal scope



### Normas oficiales mexicanas: concepto, antecedentes y aplicación legal

For those who work in the national health system, it is not uncommon to hear and apply the Mexican Official Norms (NOM), however, little is said about its origin, legal implications and legal basis. The NOM are technical regulations containing the information, requirements, specifications, procedures and methodologies that allow different government departments establish measurable parameters to avoid risks to people, animals and the environment.<sup>1</sup> They are mandatory regulations, issued by the competent agencies, in accordance with the purposes set forth in Article 40 of the Federal Law on Metrology and Standardization, which sets the rules, specifications, attributes, guidelines, characteristics or requirements for a product, process, installation, system, activity, service or method of production or operation, as well as those relative to terminology, symbology, packaging, market or labeling, and those relating to compliance or implementation.<sup>2</sup> A major difference between the first technical norms and the current Official Mexican Norms, is that the former were issued by the President of the Republic of Mexico, using the regulatory power under Article 89, Section I, of the Constitution of the United States of Mexico. While there were no laws that could regulate the so called NOMs, these were issued on the basis of a constitutional provision. At present, given the fact that modern legal relations are becoming more complex, and that the President cannot realize all the acts personally that would permit "to provide the exact observance of the laws in the administrative sphere", it has made clear the need and desirability of the federal public administration to aid him in his work.<sup>3</sup> In our country, standardization originated by the influence of the US in the global economy, that forced the Mexican government to issue laws and regulations that regulate the use of certain features in the services. In 1986 with the entry of Mexico in the General Agreement on Tariffs and Trade, which was launched in 1947, and in 1995 it was converted into the World Trade Organization, converted into an

international regulatory collegial body, which conditioned Mexico implement the recommendations of the International Organization for Standardization (ISO), and other international organizations, to create its own standards, which gave rise to the Federal Law on Metrology and Standardization.<sup>4</sup> As can be seen, the NOMs were created to regulate the use of certain features on services and products, so that the objective of the NOMs is to regulate matters of high technical expertise to comply with the obligations set out in regulations or laws.<sup>5</sup> Safety and health at work is regulated by various provisions contained in our Constitution, the Organic Law of the Federal Public Administration, the Federal Labor Law, the General Law on Health, among other legal regulations.<sup>6</sup> What happens when NOM are broken? Whoever fails to comply with NOM may be entitled to penalties, closures or including in case of the lack of compliance with NOM, puts at a risk of jeopardize the health or integrity of the consumer, the destruction of products.<sup>7</sup> The NOM regulates many aspects of our lives, which are related to health and include: water, food, household products, prevention, health facilities, among others.<sup>8</sup> In Mexico NOM had been used to establish guidelines for clinical management of various diseases that include: NOM-008-SSA3-2010 for integral treatment of overweight and obesity; NOM-006-SSA2-1992 for the prevention and control of tuberculosis in primary health care; NOM-007-SSA2-1993 care of women during pregnancy, childbirth and postpartum and newborn, and criteria and procedures for providing the service; NOM-010-SSA2-1993 for the prevention and control of infection by HIV, and others for prevention, detection, diagnosis, treatment and epidemiological surveillance of diabetes, cervical and breast cancer, cholera and other diseases.<sup>9</sup> It has been considered inappropriate to try to convert the NOM into clinical practice guidelines, since they are not the object of the NOM. As already mentioned previously, the NOM regulates matters of high technical expertise to comply with its

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established obligations in the regulations or laws. Revising the General Health Law, in which little reference to NOM is made. It is mentioned in Article 13, Section AI reports that Mexican Official Rules shall be subject to benefit throughout the national territory, health services in the areas of general health and verify its fulfillment; Article 42 states that the Ministry of Health will provide NOMs of health to the Secretariat of Finance and Public Credit for personal insurance for medical and hospitalization expenses; Article 195 states that the Ministry of Health will issue the NOMs that shall be subject to the process, product specifications referred in this title. Medicines and other health products will be regulated by the Pharmacopoeia of the United Mexican States.<sup>10</sup> While it is true that the NOM is mentioned in other articles of this legislation, it is not established that it should be considered as guidelines of medical attention. That is why, trying to use the NOM as guidelines of medical attention process can be considered an error, which originated to be put in use in the aspects for which were not created for. A few years ago, Clinical Practice Guidelines were published by the Ministry of Health, which are an element of rectory in health care, that aims to establish a national benchmark to favor making clinical and management decisions based on supported recommendations, in the best possible evidence in order to contribute to the quality and effectiveness of medical attention.<sup>11</sup> It is important to distinguish the scope of NOM and Clinical Practice Guidelines because it can be confusing and misapplying the current regulations in health in our country. Legally, Clinical Practice Guidelines are the guiding criteria in health care. And NOM regulates health-related aspects that include: water, food, household products, prevention and sanitary facilities. In the medical units and medical practice, it should be considered complementary, and compliance with them is mandatory. But their legal scopes are different. Understanding and correctly applying existing regulations on health, helps provide quality health care and enables providers of health services, identify clearly the responsibilities of all members of health teams, from senior management to operational staff.

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R. Gutiérrez-Vega  
*Hospital General de México "Dr. Eduardo Liceaga",*  
*Mexico City, Mexico*  
*E-mail address: rafaelgutierrezvega@gmail.com*