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Legal thoughts on the implications of cost-reducing guidelines for the quality of health care

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Abstract

Health care expenditures in European countries are increasing. Many cost containment mechanisms have been developed, one of which is the introduction of clinical practice guidelines in binding legislation. In developing recent patients' rights laws, many legislators refer to practice guidelines when specifying the right to quality in health care. The courts often follow this example. Initially, practice guidelines were used to improve the quality of care. Recently, their potential to reduce costs is being discovered by policy makers and compliance with the cost-controlling guidelines is mandatory and subject to financial sanctions. This article will question the impact of the 'new generation' guidelines aimed at reducing health care costs and their impact on the quality of care, in particular. The authors will analyse whether a physician, in case of a conflict with a patient, who claims that his right to quality care has been violated, can defend himself in court by stating that he complied with 'financially' inspired guidelines, especially now that non-compliance with these guidelines is sanctioned.

Keywords: Clinical practice guideline (CPG); Cost containment; Medical liability; Quality in health care; Health care expenditure

1. Introduction

Clinical practice guidelines (CPGs) are becoming a new reality in medicine, especially, in policy issues concerning health care. Initially, these guidelines were developed solely by the medical profession and used predominantly by physicians with the intent to reduce clinical variation and to further enhance the quality of health care. However, their role is now expanding and changing, whereby more and more guidelines aimed at the reduction of health care costs (hereinafter: cost-reducing guidelines) are introduced. These guidelines are based on the so-called 'classic' clinical practice guidelines but have been more refined or elaborated by or with the involvement of other, often governmental bodies, than the medical profession,

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with the aim to control health care costs. The main question in this paper will deal with the possible impact of these cost-reducing guidelines aimed, not only at enhancing the quality of health care, but also at reducing health care costs. Consequently, it is not our intention to conduct an analysis of the so-called 'classic' practice guidelines in this article. Instead, the cost-reducing guidelines, developed by several different (government) organizations which are increasingly incorporated into binding legislation, will be analysed. The question is whether these cost-reducing guidelines have an impact on a patient's right to quality care. In order to clarify this impact, the right to quality care in recent patients' rights laws will first be discussed. In this discussion (Section 2), it will become clear that the legislator and the courts refer mainly to the so-called 'classic' practice guidelines in specifying the right to quality care. One may wonder whether the use of the cost-reducing guidelines in this context will have an impact on the right to quality care. In Section 3 we describe the increasing use of cost-reducing guidelines by policymakers. We will show how policy makers increasingly issue laws that refer to or incorporate such cost-reducing guidelines. Additionally, in contrast to the so-called 'classic' practice guidelines developed by the medical profession itself, the cost-reducing guidelines developed by policy makers aim at reducing health care costs and impose sanctions on any physician who does not comply with them (Section 4). Next, we will deal with the question whether these cost-reducing guidelines can be referred to by a physician in court, in case of a conflict with a patient, who claims that his right to quality care has been violated by adhering to such guidelines too strictly? Can a physician hide behind a cost-reducing guideline that he had to follow and for which sanctions are provided in case of non-compliance, even if a patient is claiming that the physician should have acted in another way? Suppose a patient argues that he did not receive quality care, e.g. when a physician did not prescribe a specific pharmaceutical because the patient did not meet the legal requirements embedded in a cost-reducing guideline to receive a reimbursed product. May the physician be held liable by the patient for not prescribing the pharmaceutical in accordance with the criteria in the legally binding guideline in order to avoid financial sanctions? These questions will be the subject of our analysis in Section 5.

2. Right to quality health care and the reference to 'classic' practice guidelines in legislation on patients' rights

Patients' rights in Europe are on the move and getting more of a legal basis in legislation and regulation, since the draft of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine) on 4 April 1997. Several European states have recently expanded their legislation with a law on patients' rights. Most prominently, this was the case in the Netherlands [1], France [2] and Belgium [3]. Looking at the different patients' rights laws, similar rights can be identified, among them, the right to quality health care. This right entitles the patient to conscientious, high-quality health care, in accordance with the applicable medical standards and the current scientific achievements. When we further analyse the right to quality in health care, it seems that practice guidelines play a significant role in determining the content of the right. Both legislators and judges devote great attention to the concept of guidelines.

The *Belgian Act on Patients' Rights*, for example, introduced the right to quality health care in article 5. This article stipulates that every patient, with respect to his human dignity and self-determination and without any distinction, is entitled to quality care that fulfils his needs. The precise implication of this expression is further explained in the explanatory memorandum, requiring a physician to act according to 'the applicable standards and the current state of scientific knowledge' [4]. In other words, article 5 makes it mandatory for a physician to act as a '*bonus medicus*' [4]. However, what does 'acting in accordance with the applicable standards and the current scientific knowledge ('*bonus medicus*')' mean? The applicable standards refer, among others, to guidelines and protocols set up by the medical profession. They contain rules concerning the medical profession, as well as technical rules that can be used either as a standard, or as guidance in malpractice cases. When deciding whether a physician acted as a '*bonus medicus*', a *judge* needs to establish what the physician should have done in the particular case and not what is commonly done [5,6]. Thus, when making a decision on the case, the judge can rely on protocols and guidelines issued by medical organiza-