

RESPONSIBILITY OF THE HEALTHCARE FACILITY MANAGER WITHIN THE QUALITY SYSTEM IN HEALTHCARE – BETWEEN MANAGEMENT AND LEGAL RISK

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Abstract. This article addresses the issue of the Healthcare Facility Manager's responsibility within the context of implementing quality and patient safety systems, with particular emphasis on the Act of June 16, 2023, on Quality in Healthcare and Patient Safety. The aim of this study is to analyze the scope of the Manager's duties and to assess to what extent the new legal regulations shape their role as the guarantor of quality and safety of healthcare services. The article is interdisciplinary, combining legal, organizational, and ethical approaches. The results may serve as a starting point for further research on the implementation of the Act on Quality in Healthcare and Patient Safety, and on the relationship between the formal responsibility of the Manager and the actual management conditions within the healthcare system.

Keywords: quality in health care; management of a healthcare entity; patient safety; accreditation standards; manager of a healthcare facility.

INTRODUCTION

The quality of medical services is currently a key element in the management of medical facilities in the face of growing legal and social demands. In Poland, this issue gained particular importance after the socio-economic transformation, and the role of the state in shaping the culture of quality is constantly increasing [Jopkiewicz 2013, 131]. The contemporary healthcare system is based on the assumption that patient quality and safety are paramount values, and their guarantor is the Healthcare Facility Manager. The issue of the Healthcare Facility Manager's responsibility constitutes one of the key, yet most ambiguous, areas of modern medical law. The Manager is legally obliged to ensure conditions that enable the safe and lawful provision of healthcare services, while simultaneously acting as the guarantor of quality within the healthcare entity. The new Act of June 16, 2023, on Quality in Healthcare and Patient Safety, strengthened this obligation, assigning the Manager a wide scope of organizational, ethical, and legal responsibility.

In practice, this means that the Manager is responsible for almost all aspects of the healthcare entity's functioning, from the quality of medical procedures and compliance with patient rights, to the safety of staff and patients. This responsibility encompasses both the formal legal and the axiological dimensions, yet the real possibilities for its execution are often limited by systemic, organizational, and financial conditions. The literature increasingly suggests that this is a model of "responsibility without agency" a situation in which the person managing the facility is accountable for outcomes over which they do not have full control¹ [Bovens 2007, 447-68].

1. THE CONCEPT OF QUALITY IN HEALTHCARE – THEORETICAL AND AXIOLOGICAL CONTEXT

The category of quality in healthcare is multidimensional, evolving from the simple provision of clinical safety to the comprehensive management of processes, systems, and patient experience. Theoretically, this concept integrates legal, managerial, economic, and ethical perspectives. Understanding this interdisciplinary context is crucial for a proper assessment of the Manager's responsibility. In the traditional model of paternalistic medicine, the quality of service resulted from the physician's authority and competence, rather than from standardized procedures. It was only in the second half of the 20th century, with the development of quality management concepts (TQM, ISO, EFQM), that the focus shifted from individual professional liability to organizational and systemic responsibility.

Nevertheless, it should be stated that quality in historical terms has accompanied man since the beginning of civilisation [Dobska and Dobski 2012, 11]. And so since ancient times, there has been a dispute over a universal definition of quality. It also seems that as long as the world is evolving and technological progress is constantly increasing, there will not be a single definition of quality accepted by all [Ćwik 2023, 45-46]. Ancient Babylon became the cradle of the concept of quality, where the first documented records of quality can be found. Already in ancient times, a set of laws, dispositions and sanctions was established in the form of legislation. The Code of Hammurabi (18th century BC), considered to be the oldest in the world, contained a comprehensive code of laws and defined a system of penalties for the improper

¹ An example is the Act of 8 June 2017, on the method of determining the lowest basic salary of certain employees employed in healthcare entities (Journal of Laws of 2022, item 2139), which limits the influence of healthcare entities' Managers on shaping the level of employee salaries. The annual statutory wage increase exceeds the dynamics of the increase in the valuation of services financed by the NFZ (National Health Fund), which, in the absence of reimbursement for over-performance, leads to a systematic increase in hospital debt, and consequently, to the deepening of the public finance sector deficit.

performance of services was based on the laws of the talion. The code is a set of casuistic laws and was also applicable to the industry today called medicine. In the Code of Hammurabi we find references to: "If a physician inflicts a severe wound with a bronze knife and kills the patient, or if he opens a swelling and destroys his eye, the physician's hands must be chopped off" [Garbacz and Guziak 2012, 11; Seyda 1962, 10]. The first quality standards emerged in the Middle Ages, were developed by merchants and craftsmen and set a certain way of behaviour for both guild members and their apprentices [Kowalczyk et al. 2010, 79].

Quality found its way into the circle of interest of science. Qualitology as a science of quality into the canons of the sciences was introduced in the 1970s by Professor R. Kolman. It is still a young scientific discipline and is still in its formative stage [Hamrol and Mantura 2002, 15]. Despite the formation of an interdisciplinary field of knowledge, quality science, defining the concept is not an academic problem, because each company, having recognised the expectations of customers and its own capabilities, must define what quality is for it and formulate it for its own use [Blikle 2014, 36].

When considering 'quality' and its existence, it is important to state that it is a completely abstract and therefore intangible concept. Quality arises when the purpose to be served by the service or good purchased is satisfied. The fulfilment of a health service sets the goal of taking care of health. A. Czubala defines quality as "the degree to which buyers' expectations are met. A service has quality if its realisation meets or exceeds the expectations of purchasers" [Grzebieluch 2013, 68].

In attempting to define quality and medical services, it is necessary to look at the essence of service as such, which is an overarching concept. Analysing the literature in search of a definition of service, it can be concluded that "a service is a set of values, activities and processes and the interactions occurring between an entity that needs them and an entity that is able to provide them in order to satisfy those needs" [Wiśniewska 2016, 19-20]. Referring to the medical service, it is a specific type of service and its element is the health service. Pursuant to the Act of 15th April 2011 on medical activity,² a healthcare service is an activity aimed at preserving, saving, restoring or improving health, as well as other medical activities resulting from the treatment process or separate provisions regulating the principles of their performance. The nomenclature adopted in the Act indicates the sequence of consecutive activities necessary to achieve an appropriate therapeutic effect [Walków and Witczak 2012, 209].

It is worth noting that the process of providing a medical service is multifaceted. According to the definition quoted above, it is a process that results

² Act of 15 April 2011 on therapeutic activity, Journal of Laws No. 112, item 654.

in the production of an intangible good that satisfies the needs of the patient. A characteristic of health services, like other services, is its intangible nature. A health service is specific in its nature. Its provision is linked to the good that is subjectively felt to be the most important for a person, namely his or her health. Furthermore, a medical service is classified as a professional service characterised by a high level of individualisation, a disparity of knowledge between the patient and the provider [Korczyńska 2012, 68]. The most characteristic feature of a health service is the psychological complexity of the process of its provision, including the stress resulting from crisis situations affecting difficult decision-making. The next characteristic is the interaction at the level of patient and medical staff. The attitudes of both parties play an important role in this interaction. The specificity of the medical service provided is related to the fact that it is a type of professional service [Waszkiewicz and Białecka 2012, 260].

The specificity of medical services was well defined by A. Siciński, who stated that “modern science-based medicine, even if it becomes even more scientific than it is today, if it wants to be effective, should take into account that the object of its interests and treatments are people – ‘objects’ that are not necessarily rational, guided in their actions not only by scientific principles, but by various beliefs, ideas, ideals, emotions, making the most varied, multifariously conditioned choices. Knowledge of judgements, beliefs, attitudes about human health is and will be a condition for the effectiveness of even the most ‘scientific’ medicine. The provision of medical services exposes the human being: on the one hand, the doctor (his/her personality, influence on the nature of the relationship with the patient), and on the other hand, the patient with his/her needs and expectations. The unique nature of medical services is also linked to the special role of medical personnel who, in the performance of their duties, determine the health of another human being and influence the quality of the service” [Krot 2008].

Such an approach dissociates itself from the accepted dogma of neoclassical economics of the *homo economicus* model, in favour of the *homo satisfaciendus* model. The paradigm of the figurative economic man (*homo economicus*) is characterised by an infinite capacity to make rational decisions according to the principle of minimax, i.e. maximising benefits while minimising costs; it refers to a rational decision-maker making optimal choices under fully informed conditions, able to assess risks and acting consistently [Polkowska 2011, 88]. Given the characteristics of the medical service, the above has been replaced by a ‘bounded rationality’ model. It takes into account incompleteness of information and other suboptimal conditions (time pressure, conflicting stakeholder objectives, etc.). Unlike the neoclassical model, intuition and subjective assessment are as important as calculation and objective analysis. The result of such an analysis is a satisfactory rather

than an optimal outcome. “Satisfactory minimum” in the bounded rationality model is the result of decisions made by people who are in fact satisfied with sufficiently satisfactory solutions without seeking the optimum. Thus, behavioural economics verifies neoclassical assumptions while drawing on the contributions of other scientific disciplines, mainly cognitive and social psychology and, increasingly, neuroscience [Szczech-Pietkiewicz 2020, 28].

“The problem of quality of health services is one of the basic ones for the functioning of health protection” [Kędra and Chudak 2011, 83]. Just like the concept of quality itself, the definition of quality in health care is a multifaceted and multidimensional concept and depends on the perspective of the stakeholders: patient, provider and payer. As in any of the quality management systems, so in medical services a special place has been reserved for the customer – the patient, whose expectations deserve special attention [ibid., 86]. The World Health Organisation’s definition of healthcare quality states that it is “the degree to which health services involving individuals and populations increase the likelihood of achieving expectations for treatment outcomes and demonstrate compliance with current and professional knowledge.” “Defined by the Joint Commission on Accreditation of Healthcare Organisations, it is the most common emerging definition of healthcare quality, which defines quality as the degree to which any service provided to a patient, delivered in accordance with current knowledge, results in a likelihood of achieving the desired outcome of care and a reduction in the likelihood of adverse outcomes” [Bembnowska and Joško-Ochojska 2015, 458].

The pioneer of healthcare quality research in the 1960s was A. Donabedian, who is now recognised as the founder of the concept of quality in medicine. When he published *Evaluating the Quality of Medical Care* in July 1966, he could not have predicted that it would become the most cited paper in public health for the next five decades. What’s more, this publication became the foundation of his groundbreaking research on the theory and practice of quality management and the inspiration for the development of health services science. “According to his conception, quality is the kind of care in which the measurable good of the patient is maximised, taking into account the balance of expected benefits and losses accompanying the care process in all its elements” [ibid.].

A. Donabedian has conducted research involving different population groups, focusing on the quality of healthcare. According to his model, improvements in the structure of the care system should translate into better clinical outcomes, which in turn lead to improved patient health. As a result of these analyses, he proposed a concept for assessing quality of care based on three key elements: structure, process and outcome. However, he emphasised that if even one of these aspects fails, there can be no high quality health care services. A. Donabedian also pointed out that efforts to improve these three areas must be closely linked to genuine concern for patients’ needs.

Despite the fact that A. Donabedian devoted his life to research in the field of healthcare quality then, at the end of his life, he was often hospitalised and observed a system that, he claimed, “does not work” from the patient’s point of view. Optimistic to the end and knowing the social, emotional and ethical aspects of quality improvement, Donabedian stated: “Healthcare is a sacred mission... a moral enterprise and a scientific endeavour, but fundamentally not commercial. We don’t sell a product. We don’t have a consumer who understands everything and makes rational choices – and I include myself here. Doctors and nurses are stewards of something precious... Ultimately, the secret of quality is love. You have to love your patient, you have to love your profession, you have to love your God. If you have love, you can work backwards to monitor and improve the system” [Donabedian 2001, 137-41]. Thus, the research of A. Donabedian became the premise for the construction of contemporary quality management systems.

Current legislation on quality in health care is not concentrated in a single piece of legislation and is scattered. In addition, frequent amendments to the law make it necessary to keep track of changes in many legal acts. Furthermore, the aspects that we today include in the concept of quality of health care services are found in large comprehensive legal acts. According to Article 68 of the Constitution of the Republic of Poland, every citizen has the right to health care and the right to healthcare services financed from public funds. The Act on Patients’ Rights and the Ombudsman guarantees the patient the right to health services corresponding to the requirements of current medical knowledge, to reliable information on the state of health, to respect for intimacy and dignity, in particular during the provision of health services, to respect for private and family life, to pastoral care [Michalak 2011, 170; Wroński, Cywiński, and Bocian 2008, 42].

The topic of quality is not new in the Polish healthcare system, specific solutions have been in place for many years, such as the accreditation system, reporting and monitoring of adverse events, patient satisfaction surveys, and the implementation of medical records [Twarowski 2024]. As early as 2017, a draft law on quality in health care and patient safety appeared on the website of the Government Legislation Centre, with the assumption that it would become effective in 2018. Despite widespread criticism, work on the bill was not discontinued and a new version of the proposed law appeared in the Government Legislation Centre on 22 July 2022. After many years of heated discussion in the public domain on the shape of the legislation to ensure proper quality in the provision of health care services and thus patient safety, the Act of 16 June 2023 on Quality in Health Care and Patient Safety³ came into force on 8 September 2023, replacing the Act of 6 November 2008 on Accreditation in Health Care.⁴

³ Journal of Laws of 2023, item 1692.

⁴ Journal of Laws of 2016, item 2135.

2. THE QUALITY SYSTEM IN POLISH HEALTHCARE – LEGAL ASPECTS

The introduction of the new Act on Quality in Healthcare and Patient Safety opened a new stage in the perception of quality in healthcare. The evolution of legal regulations concerning quality indicates that the real challenge no longer concerns the mere existence of quality systems, but rather the way they function within the context of the organizational culture of healthcare, which redefines the understanding of the Healthcare Facility Manager's responsibility.

Compared to its predecessor, the new Act is not an entirely innovative solution, but it is a more comprehensive regulation that takes into account not only the accreditation process, which is *de facto* a voluntary procedure, but also introduces obligatory quality elements for healthcare entities.

As stated in the justification for the draft Act, the purpose of the legislation is to implement legal and organizational solutions that will comprehensively and coordinately realize healthcare policy priorities in the area of quality. The subject of regulation covers solutions in the scope of: 1) Authorization (Provisions of Chapter 2); 2) Internal Quality and Safety Management System (Provisions of Chapter 3); 3) Accreditation (Provisions of Chapter 4); 4) Medical Registers.

The Act introduces new solutions in strategic areas of the healthcare system and imposes additional obligations on the management of healthcare entities. In order for a hospital to provide healthcare services financed from public funds, it will be necessary to obtain authorization issued by the President of the National Health Fund. The purpose of the authorization is to confirm that the entity providing medical services financed from public funds meets the conditions for the provision of healthcare services as defined in the regulations issued pursuant to Articles 31d and 31da(1) of the Act of 27 August 2004 on Healthcare Services Financed from Public Funds.⁵ This requirement simultaneously constitutes one of the conditions for obtaining authorization, as specified in Article 7 of the Act. The second mandatory condition is the implementation of an internal system, which is defined in Article 18 of the Act.

The Act introduces a mandatory requirement for healthcare entities to establish an internal quality and patient safety management system, irrespective of whether they are financed from public funds. Within this internal system, entities providing medical services are obliged, pursuant to Article 18(3) of the Act, to identify the risks of adverse events and to monitor such events, to determine priority areas for improving the quality and safety of healthcare services, to define criteria and methods for supervising quality and safety, to monitor quality indicators, and to conduct patient satisfaction surveys.

⁵ Journal of Laws of 2024, item 146.

A careful analysis of the explanatory memorandum to the Act indicates that healthcare entities will also be required to appoint teams responsible for the assessment and analysis of adverse events and to create the necessary conditions for their effective operation. It is worth emphasizing that the draft Act introduces provisions concerning the protection of medical personnel in connection with the reporting of adverse events. This protection is intended to encourage staff to disclose as many adverse events as possible, without fear of sanctions or retaliatory measures, thereby supporting the development of a culture of safety within patient care.

The implementation of these solutions corresponds to the directions indicated in international research and literature, which emphasize the importance of a systemic approach to a modern organizational culture based on transparency and a culture of learning. The concept of “no-blame culture”, promoted by the Institute of Medicine in its report *To Err Is Human*, assumes that employees should not be punished for errors but rather analysed for the systemic causes of events [Kohn, Corrigan, Donaldson, et. al. 2000]. The author of the book *To Err Is Human* argues that the problem is not bad people in healthcare, but good people working in bad systems that need to be improved in terms of safety. Nevertheless, newer concepts, such as “just culture”, emphasize the need to balance individual responsibility with systemic analysis of events – even if this means responsibility for predictable and preventable errors [Parker and Davies 2020, 646-60]. In the Polish medical environment, where a culture of formal responsibility often prevails, implementing a transparent and supportive management atmosphere can significantly improve the quality of medical services and patient rights. Empirical studies confirm that in a blame culture, as many as 42% of error reports directly blamed a specific individual, significantly limiting the educational and corrective dimension of the patient safety system [Cooper, Edwards, Williams, et al. 2017, 455-61]. Furthermore, the results of a study conducted in the nursing environment showed that a developed just culture fosters open incident reporting, increases employee trust, and subordinates responsibility to the clear principle of proportionality [Logroño, Al-Lenjawi, Singh, et al. 2023, 348]. Similar conclusions come from other analyses conducted at the medical and management levels – systems equipped with clear rules and leadership support promote incident reporting and foster more effective learning [Pozzobon, Sears, and Zuk 2024, 44-55].

In the context of management, psychological safety also plays a key role, meaning a team’s sense of psychological safety, enabling them to report errors without fear of repercussions. A study published in the *Journal of Patient Safety* demonstrated that collaborative leadership, shared responsibilities, and a feedback system are crucial for building a culture conducive to reporting problems [Słowińska 2015, 54-57]. In turn, analysis of NHS and WHO

data emphasizes that healthcare institutions should strive for transparency and the creative use of errors as a source of systemic learning.⁶

Recent evidence suggests that public health structures not only promote but actually require health institution managers to shift from an administrative to a quality-oriented approach through the active implementation of complaint systems, monitoring, internal training, and transparent audits.⁷ In this context, leadership involves implementing policies that enable both the prevention of errors and their constructive explanation.

Referring to the statutory obligation to report adverse events, introduced by the Act on Quality in Healthcare and Patient Safety of 2023, most healthcare institutions remain at an early stage of implementing monitoring systems. This conclusion arises from a 2024 study conducted by the Patient Rights Ombudsman, which examined the functioning of the reporting and monitoring system for adverse events in hospitals. The study revealed significant variation in the level of organizational maturity and a lack of uniform reporting standards. More than 60% of hospitals reported no more than 50 adverse events in 2023, regardless of their size or scope of activity, indicating a substantial underreporting of actual incidents.

In many facilities (approximately 40%), the reporting process still relies on paper-based documentation, while root cause analyses and the implementation of corrective measures remain fragmented. Data collected by the Patient Rights Ombudsman show that information about adverse events is mostly communicated to the management level, but only to a limited extent reaches the broader staff, which restricts the educational and preventive function of the system. The findings emphasize the need to build a safety culture based on analysis and problem-solving rather than blame attribution, as well as the importance of creating a centralized system for collecting adverse event data, enabling standardized analysis and systemic improvement of healthcare quality [Mirska 2025, 14-17].

The Act also defines the procedure for granting accreditation in healthcare as a voluntary external assessment of quality. The provisions of the Act clarify and systematize the accreditation process, particularly with regard to its course, timelines, and the participants involved. Accreditation standards in healthcare play a crucial role in improving the quality and safety of patient care. The evolution of these standards, from the 2016 version to the most recent 2024 edition, reflects the dynamic changes in medicine, technology, and societal expectations. The new standards introduce more detailed requirements, incorporating advanced digital tools, an interdisciplinary approach

⁶ See https://www.pslhub.org/learn/culture/tackling-the-blame-culture-nhs-staff-survey-results-2020-r4261/?utm_source=chatgpt.com [accessed: 03.08.2025].

⁷ Ibid.

to care, and a stronger emphasis on patient engagement [Kęp. 2024]. The Act introduces mandatory compliance with accreditation standards and provides for the possibility of revoking a granted accreditation if the standards are not met during the accreditation review.

Accreditation standards largely reflect, in a rigorous manner, the regulations in force within the healthcare system, serving as their practical implementation in the organizational and managerial spheres. Quality management in healthcare should be characterized by a patient-centred orientation, a systemic approach, and structured activities encompassing all stages of service delivery, with the active involvement of all staff – led by the management of the healthcare entity.

In the context of original research, including in-depth interviews with the management staff of healthcare entities, Hospital Managers highlighted the difficulties resulting from the growing complexity of the quality system and the scope of imposed duties, while simultaneously indicating that possessing accreditation is, in their perception, obligatory. As they pointed out, “the system demands responsibility from us without real influence,” and “it is difficult for me to learn the new quality system and all the accreditation standards.” Some respondents noted that “the new standards impose significantly more obligations; I am not always familiar with this subject matter because I am not a physician,” or “I am concerned that I do not have the capacity to personally verify such a vast scope covered by the standards.” These statements reveal a discrepancy between the formal construction of responsibility and the real capabilities of the management of healthcare entities. Managers, although burdened with legal and organizational responsibility, often do not possess adequate tools or resources to effectively implement the assumptions of the quality system. This tension between normative responsibility and practical agency is becoming one of the key challenges in contemporary healthcare management. The Act in question also provides for the refinement of the rules for creating and financing medical registers as part of the amendment to the Act of 18 April 2011, on the Information System in Healthcare.⁸

In the described system, various entities are assigned specific roles to ensure the effectiveness and supervision of service quality. The Act on Quality in Healthcare and Patient Safety assigns the Minister of Health the role of the key entity responsible for the coordination of the quality system in healthcare. The Center for Monitoring Quality in Healthcare (CMJ) functions in the system as an executive and expert institution, supporting the implementation, evaluation, and development of quality mechanisms in healthcare. In practice, the CMJ serves as the substantive background for the state’s quality policy – it collects data, conducts research, and provides

⁸ Journal of Laws of 2022, item 1555 as amended.

organizational support, contributing to the development of patient safety culture. The Healthcare Facility Manager plays a crucial role in realizing the provisions of the Quality in Healthcare and Patient Safety Act, being responsible for creating and operating the internal quality management system and ensuring the safety of services provided.

3. RESPONSIBILITY OF THE MANAGER OF A MEDICAL ENTITY

The analysis of the responsibility of the manager of a medical entity should begin by pointing to the most superior legal act that regulates this issue, namely the Act of 15 April 2011 on therapeutic activity.⁹ Article 46 of the aforementioned Act indicates that the responsibility for the management of a medical entity that is not an entrepreneur lies with the manager. Article 19 of the Act of 16 June 2023 on Quality and Patient Safety¹⁰ clearly corresponds with the quoted article, indicating that the person responsible for the operation of the internal system is the manager of the entity performing therapeutic activity within the meaning of Article 2 paragraph. 2(1) of the Act of 15 April 2011 on therapeutic activity.

This way of managing quality is also reflected in the Total Quality Management philosophy put forward in the 1950s by E. Deming, and still regarded today as one of the most perfect forms of quality management that involves the whole organisation.

By doing a search of the most well-known certified quality management systems, it is important to recognise, and top management involvement is the key to managing long-term success through customer satisfaction. Thus, the involvement of the head of the treatment entity as the person responsible for running the internal system is most likely to come from the most excellent quality management philosophies.

Turning directly to the role and responsibility of the manager of a healthcare entity under the Quality and Patient Safety Act, the legislator has used the concept of a healthcare entity. This therefore means that certain provisions of the Act, including those sanctioning the duties and responsibilities of managers, apply not only to healthcare entities, but also to professional practices. At the same time, the provisions of the Act do not mention a manager within the framework of Article 2 of Healthcare Quality Act. Thus, it is necessary to refer to the regulations contained in the content of Article 2, but of the Act on therapeutic activity. Based on this regulation, the manager is both the director in a public institution and the management board in a therapeutic entity run in the form of a capital company.

⁹ Journal of Laws of 2024, item 799.

¹⁰ Journal of Laws of 2023, item 1692.

With regard to individual and group professional practices, the function of a manager is also performed by partners in partnerships or civil partnerships and by a sole trader [Łokaj 2023].

Analysing the duties of the manager of the healthcare entity, let us start with the most obvious ones and those that stem directly from the provisions of the Act. Thus, as indicated earlier, that the person responsible for running the internal system is the manager of the entity performing therapeutic activity. Within the framework of the above, the legislator has defined the tasks of the responsible person, which include: 1) conducting a root cause analysis of the adverse event; 2) providing the resources and information necessary to adequately monitor the quality and safety of the healthcare services provided; 3) the development of documents setting out the principles, procedures, methods and job descriptions referred to in Article 18(1).

At this point, it is worth participating in managerial competencies and their application within the framework of the discussed topic. A modern manager can perform his/her basic managerial roles and functions effectively and carry out tasks efficiently if he/she has not only the appropriate general and specialised knowledge, experience, the desired set of personality traits, abilities, intelligence, but also basic, specific managerial skills, fixed as habits [Ćwik and Zbroja 2013, 131]. One of the techniques that will find application in the implementation of the tasks set out in the Quality and Patient Safety Act will be the effective delegation of decision-making authority to lower levels of management. "Proper delegation saves time for the most important functions of a manager" [Królczyk and Królczyk 2012, 37]. It is relatively easiest to delegate simple and routine tasks, but respecting knowledge and showing care for staff development, the leader also assigns more difficult tasks. A subordinate to whom tasks and powers have been delegated becomes responsible to the manager for undertaking the relevant task and the manager remains responsible for causing the task to be carried out, delegation leads in fact to double responsibility (according to the principle of *delegatus non potest delegare*) [Dźwigoł-Barosz 2011, 149]. By delegating duties and powers together with resources, the supervisor transfers full direct responsibility to the subordinate, while himself retaining indirect responsibility for deciding to whom and what tasks he has delegated. However, he or she cannot relinquish the duty to supervise his or her own work or to ensure that subordinates perform the tasks assigned to them. Thus, to quote Ch. J. Barnard, who formulated one of the most important principles of decision-making thus: "the beautiful art of deciding consists in [...] not deciding what someone else can decide" [Barnard 1938, 194].

Although the Act formally assigns numerous responsibilities to the manager, explicitly stating that the person responsible for maintaining the internal system is the manager of the entity performing medical activities

within the meaning of Article 2(2)(1) of the Act of 15 April 2011 on Medical Activities, hereinafter referred to as the “responsible person,” their actual authority and resources may in many cases be insufficient to effectively perform these tasks. The manager often becomes the “point of contact” – responsible for systems, procedures, and oversight, but does not always have influence on clinical or financial decisions. Therefore, one can speak of “systemic responsibility” – formally assigned, but not always enforceable in practice. Therefore, in this context, it should be clearly indicated that the entire process of compliance of the medical facility with the provisions of the Quality and Patient Safety Act is the responsibility of the manager of the medical facility, i.e. the person who represents the entity externally and manages and supervises the entire process. Admittedly, although it is clear that the function of the healthcare entity manager comes down to supervising the functioning of the internal quality and safety management system, the responsibility is already personal.

This view is also expressed by the District Court in Łomża (ref. no. III P 62/24), which states that quality management in healthcare should be characterized by patient focus, a systemic approach, and organized action encompassing all stages of service provision, with the active involvement of all staff, led by the healthcare facility’s management. The quality of medical services is interdisciplinary and encompasses both compliance with current knowledge and standards and elements relevant to the patient. The award of accreditation confirms that management ensures the facility operates in accordance with good practice standards.

Having analysed the provisions of the Act, one does not find premises preventing the delegation of powers and tasks to subordinate persons. Therefore, these persons, within the framework of the tasks performed by them, will only be liable towards the medical entity on the basis of responsibility resulting from the proper performance of the tasks entrusted to them. This responsibility is differentiated with respect to employees hired on the basis of an employment contract, where the responsibility is regulated by the Labour Code, and persons performing tasks on the basis of civil law contracts, the responsibility will be regulated on the basis of the Civil Code. Thus, if the non-compliance caused a specific damage to the healthcare entity, resulting in liability for damages, e.g. a claim by a patient or the imposition of a penalty by controlling entities, the healthcare entity has the possibility of a recourse claim also against a specific employee, who, for example, by using certain equipment in the course of providing services, was the direct cause of the given damage [Łokaj 2014].

The above considerations referred explicitly to the premise verbalised in the Quality and Patient Safety Act for the liability of the manager of a healthcare entity. However, an analysis of the content of the Act indicates other

obligations on the part of the manager that may result in professional liability. The first premise is found in Article 4 of the Quality and Patient Safety Act. This provision refers to quality indicators. While the indicators themselves are not concretised in the Act, it is specified that they will be measured in three areas: clinical, consumer and management. Article 15 of this provision provides statutory authority for the President of the National Health Fund to monitor indicators, publish them on the Fund's website, and bill healthcare services based on the achievement of quality indicators. These provisions establish the manager's responsibility as a manager who influences the values of the indicators achieved by the facility and, consequently, the amount of the "financial bonus" resulting from the correction indicators established by the President of the Fund. Another obligation relating on the head of a healthcare entity under Article 7 of the Quality and Patient Safety Act is to obtain authorisation. Authorisation is a novelty introduced by the Quality Act. It is a prerequisite for hospitals to carry out treatment activities within the profiles of the basic hospital care system. Therefore, a hospital which wants to enter the so-called hospital network and have a guarantee of concluding an agreement with the NFZ, without a competition procedure, must obtain such authorisation. It is therefore an obligatory element of entry into this system [Rożdżeński 2024]. Therefore, the provision in question imposes an obligation to have authorization and for the manager an obligation resulting from constant supervision over the process of obtaining authorization.

This model of managerial responsibility reveals a significant legal and organizational problem. The dilemma of individual and collective responsibility in quality management is a key issue in contemporary medical law and healthcare management science. In the practical operation of healthcare facilities, responsibility for the quality and safety of services is multi-leveled – extending from systemic decisions made by public institutions, through the organizational responsibility of the individual, to the individual actions of medical personnel. The manager of a healthcare facility occupies a special place in this system – formally a guarantor of quality, but in reality, they operate under the shared responsibility of the entire team and with limited influence on all processes occurring within the organization. This situation creates a dilemma between the scope of their personal legal responsibility and the dispersed, collective nature of actions affecting the quality of healthcare services. As a result, the line between individual and collective responsibility becomes blurred, leading to ambiguity in assessing culpability and perpetration in cases of quality standard violations or adverse events. The analysis of this phenomenon is of significant importance for the interpretation of the statutory duties of managers, as well as for the development of an organizational culture based on shared responsibility and learning from mistakes, rather than on sanctioning individuals.

CONCLUSION

The Quality and Patient Safety Act is another piece of legislation that imposes obligations on the manager of a healthcare provider. While it does not in itself indicate a sanction for not fulfilling this duty, its content has consequences that are a sanction set out in other legislation or professional consequences incurred. The manager of a healthcare entity has an important role in the management of a healthcare facility. In the health care system, the organisation of the hospital is crucial for the quality of health services and patient safety. The responsibility for organisation lies with the manager of the healthcare entity, who bears the consequences of organisational errors. Far-reaching conclusions indicate that these errors, resulting from mismanagement, lack of supervision or faulty organisation of processes, can lead to serious health, legal and financial consequences. The legal bases for the liability of the manager of the treatment entity are:

1. Civil liability: relating to liability for damage caused to patients or third parties, often as a result of organizational negligence (Articles 415 and 430 of the Civil Code). Under civil law, the liability of the manager of a healthcare facility derives from two basic regimes: contractual liability and tort liability. Both of these legal mechanisms apply to damage caused to a patient, and may arise from both actions and omissions on the part of medical or organizational staff, for which the healthcare facility as a whole is responsible. As indicated by the Court of Appeal in Kraków in its judgment of February 22, 2022 (ref. no. I ACa 1134/21), failure by hospital managers to provide a patient with safe conditions constitutes a breach of due diligence, and due to the relationship of authority and subordination, pursuant to Article 430 of the Civil Code in conjunction with Article 415 of the Civil Code, justifies attributing liability to the healthcare facility. Liability understood in this way is institutional in nature. In employment relationships, liability for damage caused to patients by staff generally rests with the healthcare facility, as the employer (Article 430 of the Civil Code in conjunction with Article 120 of the Labor Code). However, in a structure based on civil law contracts, Article 429 of the Civil Code applies, imposing on the manager the obligation to exercise due diligence in the selection and supervision of contractors. In this approach, the manager's liability is not subsidiary in nature, but stems from their own organizational obligation. In cases where the manager's decisions are culpable, in particular intentional or grossly negligent, the general principle of Article 415 of the Civil Code applies, allowing for the assignment of personal liability. This construction leads to the conclusion that the manager of a healthcare facility is not only a participant in the quality system, but its guarantor in the legal and ethical sense.

However, the Draft Act Amending the Act on Patients' Rights and the Patient Ombudsman and the Act on the Emergency Notification System (RCL UD207), Article 69b provides for the possibility of imposing a fine of up to 20 times the average salary directly on a natural person holding a managerial position (e.g., a hospital director) from their personal assets if that person, in the exercise of their function, has, through their action or omission, permitted a violation of the prohibition specified in Article 59(2) or a failure to take actions necessary to discontinue a practice infringing the collective rights of patients. The justification indicates that the new authority of the Patient Ombudsman is analogous to that held by the President of the Office of Competition and Consumer Protection. Commentary on the provision of Article 106(1) of the Act of 16 February 2007 on Competition and Consumer Protection, which is analogous to the proposed Article 69b of the Act on Patients' Rights and the Patient Ombudsman: "The purpose of the regulation in question is to ensure the greatest possible effectiveness of the Act's provisions. It can be assumed that the risk of penalizing an entrepreneur will only in some cases be sufficient to discipline individuals and persuade them to behave as desired by the legislator. Personal liability may be a much more effective means of pressure in this context, persuading those responsible for managing the entrepreneur to act in accordance with the law." In practice, the civil liability of a manager can take various forms, and as a rule, the health-care facility is liable for damages caused by its personnel, from claims for damages and compensation by patients or employees, to recourse claims by the entity against the manager in the event of proven fault in supervision or organization.

2. Criminal liability: arising from the provisions of the Penal Code, including Articles 160, 231, and 296, concerning, among other things, endangering the life and health of patients, abuse of authority or acting to the detriment of the institution, crimes against property, official misconduct, and crimes against documentation. In the context of criminal liability, organizational errors pose a growing risk for management. An interesting example of an organizational error is liability for leaving a foreign body in the surgical site. In the case of suturing a foreign body in a patient's body, organizational errors may also occur, such as failure to assign tasks to staff members regarding material counting or improper communication between staff members. It is worth noting the judgment of the District Court in Zgorzelec of March 13, 2013 (ref. no. II K 63/10), in which the court noted that "an organizational error is not a case of medical malpractice, although it may involve a technical, therapeutic, or diagnostic error." One can also cite the judgment of the District Court in Słupsk of 5 December 2017 (ref. no. XIV K 54/15), where the Director

was accused of failing to fulfil his duties as director of the Provincial Hospital in S., being responsible for the organisation of optimal conditions for performing medical duties, thus exposing the patient to a direct risk of loss of life or serious damage to health (Article 160(2) of the Penal Code).

3. Professional liability: This is handled by professional self-governing bodies, such as Medical Courts. It concerns violations of ethical and professional deontological principles. This type of liability directly impacts the professional status of a physician, as well as that of those in management positions, provided they are licensed to practice medicine.
4. Ethical responsibility: Healthcare managers have a moral obligation to ensure the well-being of patients. Neglect or disregard for ethical standards leads to a loss of public trust and negative consequences for the institution's image.

A detailed analysis of the above issues is a separate subject of analysis.

An analysis of the issue also reveals an increasing need to implement *compliance* standards. Although compliance in medicine is not a new concept, it was used in a completely different field of definition. It was still known in medicine in the last century and denoted the degree of conformity of a patient's behaviour to medical recommendations. Good *compliance* in medicine corresponded to the patient's consistent adherence to medical recommendations [Borowa and Mnich 2012, 2]. The concept gradually began to be adopted in economic sciences in the 1990s during the detection of economic crimes. And the financial crisis at the beginning of the 21st century, initiated by the symbolic collapse of Lehman Brothers, led to the expansion of *compliance* to other companies and industries.

In professional business language, compliance is understood to mean compliance with applicable laws, instructions and internal company procedures. However, there is no explicit requirement in the Polish legal system for an organisation to have *compliance* structures [Chmielewski and Ciesiołkiewicz 2017, 5]. The ever-increasing number of legal norms and non-legal regulations increases the risk of non-compliance. Compliance covers every sphere of an individual's functioning in public life. Intense lawmaking activity and new regulations of national and international organisations mean that an entity, wishing to participate effectively in business, is forced to implement new solutions and at the same time minimise their risk. *Compliance*, as an interdisciplinary field, is currently undergoing intensive development. Compliance management is no longer the domain of private entities alone. Changing legislation, as well as planned regulations, codes of ethics and procedures, make the issue of compliance important for organisations in the public sector, for which legislation makes it mandatory to implement certain compliance solutions. However, the broader public sector has important

specificities that must be taken into account when implementing *compliance* solutions. In public authorities, compliance encompasses not only generally applicable law and internal law, but also organisational culture and professional ethos [Wiatrak 2021, 130-31].

Considering the analysis, it should be recognized that the current model of responsibility for healthcare facility managers, reinforced by the Quality Act of 2023, creates a tension between formal responsibility and actual agency. Although the manager is legally responsible for quality and safety, he or she often operates under limited systemic and financial influence, leading to a model of “responsibility without agency.” The expansion of formal requirements, such as an internal quality management system, authorization, and accreditation, is not always balanced by structural support and resources. This results in implementation gaps (e.g., underestimation of adverse events), ambiguity in assessing blame, and a blurring of the line between individual and collective responsibility.

Recommendations (*de lege ferenda*): Public authorities must support the development of a safety culture based on root cause analysis and the search for solutions, rather than on assigning blame, by promoting just culture and psychological safety to increase the transparency of error reporting. The Act itself has not changed employee awareness.

Consideration should be given to introducing personal liability for employees of healthcare entities entrusted with tasks within the internal quality system (based on delegation of authority), similar to official liability (for damage caused by unlawful acts or omissions while performing tasks). Such a solution would foster greater shared responsibility and more effective enforcement of quality standards, balancing managerial responsibility.

Systemic strengthening of management tools by providing managers with adequate resources and tools (e.g., digitalization, training) necessary for effective quality management and oversight of a wide range of procedures, in order to reduce the “responsibility without agency” model.

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