

# Compliance and due diligence in healthcare: international experience and implementation challenges

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## ABSTRACT

**Aim:** To analyse the international experience of applying compliance and due diligence procedures in healthcare and to identify the main challenges to their implementation.

**Materials and Methods:** The study is based on the systematisation and comparative analysis of regulatory and empirical data on the implementation of compliance and due diligence procedures in healthcare. The empirical base includes data from the U.S. Sentencing Commission and the U.S. Department of Justice Fraud Section (2019–2025), illustrating the influence of compliance and ethics programmes on organisational accountability, supplemented by legislative frameworks and case law from the United States, the European Union, and Ukraine. The assessment covered eight indicators. Dialectical, hermeneutic, comparative, analytical, synthetic, and systems analysis methods were used.

**Conclusions:** The main challenges to implementing compliance and due diligence procedures include the absence of a legislative mandate for healthcare institutions and a low level of corporate culture and ethical awareness.

**KEY WORDS:** compliance, risk, criminal offence, liability, healthcare

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## INTRODUCTION

At a time when population health indicators tend to deteriorate, healthcare plays an extremely important role in society. In international practice, compliance and due diligence procedures are attracting increasing attention, as they have proven to be effective elements of healthcare management [1, 2]. They are capable not only of improving the reputation of healthcare institutions and pharmaceutical companies but also of reducing the severity of penalties in cases of criminal offences, as is the practice in some countries (particularly the United States) [3].

## AIM

The purpose of the article is to analyze the international experience of applying compliance and due diligence procedures in healthcare and to identify the main challenges and prospects for their implementation.

## MATERIALS AND METHODS

This study is based on the author's original systematization and comparative analysis of data on the implementation of compliance and due diligence procedures in healthcare. This study is based on the systematization and comparative analysis of regulatory and empirical data on the implementation of compliance and due diligence procedures in healthcare. The empirical base includes data from the U.S. Sentencing Commission and the U.S. Department of Justice Fraud Section (2019 – 2025), illustrating the influence of compliance and ethics programs on organizational accountability, supplemented by legislative frameworks and case law from the United States, the European Union, and Ukraine. The assessment covered eight indicators – legal framework, internal policies, anti-corruption, data protection, ethics, monitoring, whistleblower protection, and risk management – allowing a comparative evaluation of the effectiveness of healthcare compliance systems

across the three jurisdictions. Dialectical, hermeneutic, comparative, analytical, synthetic, and systems analysis research methods were used.

## ETHICS

The authors declare that in preparing this article all ethical principles and rules of academic integrity were observed. All sources used in this literature review are publicly available. A citation agreement was obtained from the copyright holder.

## FRAMEWORK

The study was conducted as a fragment of the complex scientific project of the Educational and Scientific Institute of Law Taras Shevchenko National University of Kyiv «Legal support for the sustainable development of the economy of Ukraine in the context of European integration» (state registration number 0124U003297; term: 2024-2029).

## REVIEW AND DISCUSSION

The implementation of compliance and due diligence procedures in healthcare develops unevenly and progressively across different countries. This study covers the following groups of entities: 1) state and local governments, 2) healthcare institutions of various forms of ownership, 3) pharmaceutical companies, 4) distributors of medicinal products, and 5) other entities involved in the healthcare sector (such as insurance companies providing health insurance services, research institutions and organizations, professional associations of doctors and pharmacists, suppliers of medical equipment, consumables, and IT solutions in the field of eHealth, as well as international organizations and donor institutions implementing programs in healthcare, etc.). Hereinafter, the generalized term “compliance entities and due diligence procedures” is used to refer to these entities.

One of the most successful models of compliance and due diligence procedures operates in the United States, a country with one of the highest levels of corporate culture and business ethics. Compliance entities are de facto obliged to implement compliance and due diligence procedures in their activities. This requirement arose following the adoption in 1991 of the Federal Sentencing Guidelines for Organizations (FSGO) [3], which define the principles and approaches to imposing penalties on organizations. An important component of these principles is the introduction of effective compliance and ethics programs [4]. Such programs include at least eight elements: 1) standards and procedures: the organization shall establish standards and procedures to prevent and detect criminal conduct; 2)

management responsibility; 3) promotion of a corporate culture that encourages ethical conduct and a commitment to compliance with the law; 4) prudence in the delegation of authority: due care must be exercised when granting discretionary authority to avoid delegating it to individuals with a history of illegal or unethical conduct; 5) training, information, and control; 6) disciplinary liability; 7) response and improvement of the program: after detecting a violation, the organization must take all reasonable measures to eliminate its consequences and prevent similar cases in the future by improving the compliance program.

Based on the original systematization and comparative analysis of data on the implementation of compliance and due diligence procedures in healthcare, the impact of compliance and ethics programs on organizational accountability is shown to be significant, as evidenced by data from the U.S. Sentencing Commission (Fig. 1).

The data demonstrate that an overwhelming majority of organizational offenders (89,6%) lacked a formal compliance and ethics program at the time of misconduct, indicating a strong correlation between the absence of structured compliance measures and organizational wrongdoing. Only a negligible share (0,2%) received a culpability score reduction for maintaining an effective compliance program, while 58,3% experienced increased culpability due to demonstrated tolerance of criminal activity. The findings further show that proactive disclosure and cooperation remain rare (1,5%), and court-mandated compliance reform is still a frequent corrective intervention (19,5%). These results suggest that the implementation of meaningful compliance systems is both underutilized and crucial for mitigating organizational liability.

The presented assessment reflects the authors' expert judgment grounded in an analysis of regulatory provisions, compliance standards, and practical implementation mechanisms within each healthcare system. As shown in Fig. 2, the United States demonstrates the highest overall level of implementation of compliance and due diligence elements in healthcare. All assessed components are evaluated at the maximum or near-maximum level (4–5 points). This indicates that compliance is regulated by regulations and supported by an appropriate level of corporate culture with well-developed monitoring and control systems combined with ethics training and whistleblower protection measures.

In contrast, the European Union presents a more mixed picture, with high scores in data protection (5 points) due to the implementation of the General Data Protection Regulation (GDPR) and significant progress in whistleblower protection (4 points) under Directive (EU) 2019/1937. However, other elements, such as internal policies, monitoring systems, and corporate culture, remain at a moderately high but not yet fully institutionalised level (4 points). This suggests that, while the EU maintains a robust regulatory



**Fig. 1.** The impact of compliance and ethics programs on organizational accountability (systematized based on United States Sentencing Commission data)  
*Source: compiled by the authors based on [3]*

framework, compliance practices vary across Member States, reflecting differences in national governance models and healthcare management.

Ukraine, by comparison, demonstrates an initial and uneven stage of compliance and due diligence implementation. Most indicators remain at the 2–3 point level, indicating the predominance of declarative norms over practical application. The legal framework and anti-corruption measures show moderate progress (3 points), mainly due to alignment with international obligations. However, whistleblower protection (1 point) and corporate ethics training (2 points) in healthcare remain underdeveloped (Fig. 2).

A broader application of other compliance and due diligence procedures is observed in:

a) Private medical institutions focused on international investors or patients; they are interested in implementing quality risk management. The process is composed of the assessment, control, communication, and review of quality risks. Such entities are usually interested in obtaining international accreditations. For example, one of the most prestigious accreditations is the Joint Commission International (JCI), which requires the creation of internal policies on compliance and risk management, continuous monitoring of incidents, protection of patients’ rights, and strict control of clinical procedures [5]. The presence of JCI accreditation significantly increases the reputation of the institution and simplifies entry into the foreign market;

b) pharmaceutical companies. Foreign pharmaceutical companies operating in Ukraine comply with the requirements of the Foreign Corrupt Practices Act, USA, or the UK Bribery Act, which set standards for anti-corruption activities.

The due diligence procedure is also widespread in healthcare. The application of such a procedure is aimed at avoiding or minimizing potential risks when carrying out investment or other economic activities in order to verify compliance with legal norms or regulatory requirements [6].

It is not enough to formally prescribe such programs; it is necessary to ensure their implementation. If entities subject to compliance and due diligence procedures do not implement such elements in their daily work (for example, if they do not conduct training for employees, do not establish and/or provide an internal control or monitoring system), this creates risks for both the entity and investors. For example, in the case of criminal proceedings against such an entity, failure to comply with the requirements may be considered an aggravating circumstance when imposing a penalty. Such behavior is considered as liability based on reckless negligence, since the legal entity intentionally did not implement compliance programs or did not conduct due diligence procedures. This practice has already proven its effectiveness in the USA [7].

Regarding individual areas of implementation of such mechanisms in Ukraine, the following should be noted.

Firstly, compliance practices and due diligence procedures are important in the processes of digital transfor-

Compliance / Due Diligence Element	USA (1–5)	European Union (1–5)	Ukraine (1–5)
Legal framework	5	5	3
Internal policies & procedures	5	4	2
Anti-corruption mechanisms	5	4	3
Data protection	4	5 (GDPR)	3
Corporate culture / ethics training	5	4	2
Monitoring and control systems	4	4	2
Whistleblower protection	4	4 (EU Directive 2019/1937)	1
Risk management / audits	5	4	3

**Fig. 2.** Level of Implementation of Compliance and Due Diligence Elements in Healthcare of USA, EU and Ukraine

*Picture taken by the authors*

mation of the healthcare system [8, 9]. For healthcare institutions that cooperate with European partners or process data of EU citizens, it is necessary to comply with the provisions of the General Data Protection Regulation (GDPR), which guarantees the patient's right to access, correct, and delete their personal data, implement the principle of data minimization, and the obligation to notify about data leaks within 72 hours [10].

Secondly, compliance practices are implemented in the implementation of the state's anti-corruption policy in the healthcare. To some extent, the implementation of compliance and due diligence programs is influenced by international donors and partners that finance projects aimed at developing internal policies for controlling and preventing abuse, providing grant support or attracting foreign investment.

Thirdly, an indicator of the effectiveness of compliance and due diligence procedures is greater transparency and oversight of procurement, personnel appointments and reporting (such as unified electronic portals for job vacancies and procurement), which will reduce opportunities for abuse.

The term "compliance" is defined in the Cambridge Dictionary as "behavior that obeys an order, rule, or request" [11]. In healthcare, this concept encompasses a wide range of measures aimed at ensuring adherence to legal norms, professional standards, and ethical principles. At the same time, compliance is closely related to risk management, since failure to comply with rules or standards in healthcare can endanger patients' lives and health.

According to scholars, this concept is based on the following criteria: 1) the introduction of new standards and programs that are objectively capable of reducing the likelihood of illegal behavior in the future; 2) systematic monitoring of the level of compliance with legal requirements by corporate management; 3) unrestricted exchange of information between all structural units; and

4) adequate responses to violations that have already been committed, as well as their prevention in the future [12].

Compliance helps organizations develop a systematic approach to adherence to norms and standards, thereby reducing the risk of violations and contributing to business reputation and market stability [13].

The concept of due diligence in the dictionary sense means "action that is considered reasonable for people to be expected to take in order to keep themselves or others and their property safe" [14]. In Ukraine, due diligence is mostly equated with legal audit, however, it is much narrower in scope and essentially means legal examination of activities regarding compliance with legislation [15]. In the USA, compliance programs in healthcare have received strong development after the adoption of FSGO [16], which defined the principles of corporate responsibility and encouraged companies to implement control systems to reduce the risks of criminal liability. An additional incentive was provided by numerous federal laws, in particular the Health Insurance Portability and Accountability Act, which protects medical data; the Anti-Kickback Statute, which prohibits improper remuneration for patient referrals; Stark Law, which provides for restrictions on financial relationships between doctors and medical institutions [17].

Legal regulation of compliance and due diligence in healthcare in Ukraine is almost non-existent. There are no laws or subordinate regulations that would oblige healthcare institutions or pharmaceutical companies to implement such mechanisms. While, for example, the USA demonstrates a comprehensive approach to protecting healthcare: strict and clear criminal legislation is in force, regular raids and investigations are carried out, and a preventive compliance system is also in place (according to the standards recommended by the Office of Inspector General of the U.S. Department of Health and Human Services).

For example, in 2009, Pfizer Inc., one of the world's largest drug manufacturers, was charged with violating

two US federal laws: the Food, Drug, and Cosmetic Act (FDCA), regarding the illegal marketing of drugs, and the False Claims Act, regarding the submission of false data and claims for referrals to federal health care programs, in particular Medicare and Medicaid [18]. The charges were based on the fact that Pfizer and its subsidiaries marketed drugs by promoting them for off-label use, that is, for the treatment of diseases and conditions that were not officially approved by the FDA in the drug product instructions. The company employed aggressive marketing strategies that led to a significant increase in drug prescriptions, resulting in substantial financial losses for government healthcare programs such as Medicare and Medicaid, while also posing risks to patient health. In response to the accusations, Pfizer began a large-scale reform of its compliance system: to prove that the company's actions were not intentional, the company proved that it had problems with controlling individual divisions; demonstrated due diligence and a desire to eliminate the consequences of violations, and thereby reduced the size of the criminal penalty (by concluding a deferred prosecution agreement).

In most EU countries the healthcare system is focused on implementing compliance and due diligence in line with EU regulatory requirements, quality management systems ISO 9001 (quality management systems), ISO 31000 (risk management), JCI accreditation and the EFQM (European Foundation for Quality Management) excellence model. Standards that set guidelines for implementing compliance and due diligence programs include GDPR, EU Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, European Medicines Agency standards and recommendations, etc. In addition, there are additional requirements in national systems.





## CONCLUSIONS

1. The analysis of international and national practices in implementing compliance and due diligence procedures in healthcare demonstrates that they constitute an integral component of risk management. Due diligence is primarily a one-time comprehensive assessment, usually conducted before investment activities or the acquisition of a healthcare institution or pharmaceutical company, aimed at identifying legal, financial, and reputational risks that may affect a company's future operations and investment attractiveness. Compliance, by contrast, is a continuous process carried out through a set of actions designed to verify adherence to legislative, ethical, and corporate standards in the daily activities of entities subject to compliance and due diligence procedures.
2. In Ukraine, compliance and due diligence procedures in healthcare are currently at the stage of forming an understanding of their necessity and feasibility of implementation. In this context, the study of best global practices and recommendations of the WHO, EFPIA, and other international bodies appears promising. Such programmes should cover licensing and accreditation procedures for healthcare institutions, ethical standards of medical care and patient interaction, personal data protection, and the implementation of anti-corruption policies, including the prevention of conflicts of interest and the definition of "legitimate interactions" with pharmaceutical companies and insurance organisations. Equally important is the creation of training programmes to enhance the qualifications of healthcare institution managers and medical professionals in risk management. These measures will contribute to building a transparent and ethical healthcare system that meets European and global standards.

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## CONFLICT OF INTEREST

















The Authors declare no conflict of interest

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