



PROMOTING ETHICAL CONDUCT IN HEALTHCARE: THE IMPACT OF COMPLIANCE
PROGRAMS UNDER BRAZIL'S ANTI-CORRUPTION LAW AND GENERAL DATA
PROTECTION REGULATION¹

PROMOVENDO A CONDUTA ÉTICA NA SAÚDE: O IMPACTO DOS PROGRAMAS DE
COMPLIANCE SOB A LEI ANTICORRUPÇÃO E A LEI GERAL DE PROTEÇÃO DE DADOS NO BRASIL

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Abstract: The right to healthcare is a fundamental right that the State must guarantee through the provision of services to all citizens. Brazilian Health System aims to provide healthcare to everyone, promoting social justice. The legislature has created laws to keep up with the constant changes in society, such as the LGPD (Brazilian Data Protection Law) in 2018, which addresses personal data security. Compliance has evolved into an effective tool for promoting good corporate governance practices, and its implementation in healthcare aims to ensure transparency, security, organization, and control in the relationship between medical professionals, patients, and healthcare institutions. The implementation of a compliance program in healthcare can prevent ethical violations and ensure legal and ethical conduct. This article aims to analyze the impact of compliance programs in healthcare under the principles of the LGPD. This research utilized a theoretical approach, focusing on compliance, on the legislative roots, and on the LGPD. It aimed to understand healthcare professionals' implications under the LGPD, as well as to promote compliance program implementation, acknowledging data limitations in healthcare institutions. The final conclusion was that healthcare institutions must implement compliance programs to mitigate potential risks caused by the misconduct of specific employees concerning the treatment of patients' sensitive data. It is mandatory that healthcare professionals' attitudes toward personal data are guided by ethical and moral standards.

Keywords: Healthcare. Compliance programs. Brazilian Data Protection Law (LGPD). Ethics. Medical Law.

Resumo: O direito à saúde é um direito fundamental que o Estado deve garantir por meio da prestação de serviços a todos os cidadãos. O Sistema Único de Saúde (SUS) do Brasil tem como objetivo fornecer atendimento médico a todos, promovendo a justiça social. O legislativo criou leis para acompanhar as constantes mudanças na sociedade, como a Lei Geral de Proteção de Dados (LGPD) em 2018, que aborda a segurança de dados pessoais. O compliance evoluiu para uma ferramenta eficaz na promoção de boas práticas de governança corporativa, e sua implementação na área de saúde visa garantir transparência, segurança, organização e controle na relação entre médicos, pacientes e instituições de saúde. A implementação de um programa de compliance na área de saúde pode evitar violações éticas e garantir conduta legal. Este artigo tem como objetivo analisar o impacto dos programas de compliance na área da saúde sob os princípios da LGPD. Esta pesquisa utilizou uma abordagem teórica, com foco em compliance, raízes legislativas e LGPD. Teve como objetivo compreender as implicações dos profissionais de saúde perante a Lei de Proteção de Dados (LGPD) e promover a implementação de programas de compliance, reconhecendo as limitações de dados em instituições de saúde. Conclui-se que as instituições de saúde devem implementar programas para mitigar riscos potenciais causados pela conduta inadequada de funcionários específicos no tratamento de dados sensíveis de pacientes. É imperativo que as atitudes dos profissionais de saúde em relação aos dados pessoais sejam guiadas por padrões éticos e morais.

Palavras-chave: Saúde. Programas de compliance. Lei brasileira de proteção de dados (LGPD). Ética. Direito Médico.

INTRODUCTION

Healthcare covers a wide range of aspects, including social life, culture, habits, as well as disease prevention. In Brazil, the 1988 Constitution ensures that everyone has the right to having healthcare. As the importance of ethics in healthcare grows, the International Finance Corporation (IFC) has established ten ethical principles to promote responsible behavior and improve global health outcomes. Compliance involves not only legal matters, but also governance, ethics, public and private governance, risk management, and auditing. The objective of compliance is to prevent corruption and harmful acts, being based on ethics, morality, and the law. The LGPD was introduced in 2018 to protect people's privacy in the digital age, when technological advancements can sometimes result in severe violations of privacy rights.

Compliance in the healthcare industry concerns to the legal and administrative aspects of medical practice, encompassing the relationship between medical institutions, professionals, and patients, with an emphasis on ensuring transparency, security, organization, and control. The implementation of a compliance program in healthcare is crucial to prevent unethical conduct such as corruption, moral harassment, disregard for the law, misconduct, and professional ethical violations. The LGPD guidelines must also be considered to protect patient's personal data and prevent data breaches.

This research evaluates the application and impact of compliance programs in the healthcare industry based on the principles of the LGPD. The article aims to describe the historical and legal foundations of the fundamental right to healthcare, as well as the concept and purpose of compliance. Other aims are to discuss ethics in healthcare, explain the implementation of compliance programs in accordance with the LGPD in the clinical/hospital-patient relationship, and highlight the implications, crimes, and benefits that healthcare professionals, clinics, and hospitals are subject to under the legal parameters of the LGPD.

METHODOLOGICAL APPROACH

This research was based on a theoretical approach, involving a literature review in all stages of the study. Bibliographic exploration was used to provide an overview of a specific problem or situation, while documentary research focused on sources such as statistics, newspapers, laws, and jurisprudence. The research is applied and aimed at generating knowledge for practice and solving specific problems with compliance, its legislative roots, and the LGPD as the theoretical framework.

The article aims to deepen understanding of the implications, crimes, and benefits

associated with healthcare professionals, clinics, and hospitals under the legal parameters of the LGPD and to promote compliance program implementation in the healthcare sector. This study does not involve case studies and includes all populations of healthcare professionals and related institutions. However, there are data limitations due to recent laws and healthcare institutions' inadequate understanding of the need for integrity programs and data protection.

THE RIGHT TO HEALTH IN BRAZIL

Health encompasses not only the absence of diseases but also the health-disease process, which is influenced by habits, customs, and societal living (BARCELLOS, 2008; BRASIL, 2020). The 1988 Constitution of the Federative Republic of Brazil (CF/88) recognizes health as a universal right (BRASIL, 1988). To guarantee this right, the Brazil's Health System (SUS) was established to promote social justice and ensure care for everyone (SARLET, 2007). The historical development and legal basis of the right to health in Brazil are connected to sanitary movements and to the Brazilian Sanitary Reform, initiated in the 1970s (SILVA E., 2022).

The infra-constitutional basis of SUS includes the Organic Health Law (Law No. 8,080/1990) and Law No. 8,142/1990 (MATTA, 2007). The Brazilian Constitution of 1988 enshrines fundamental rights tied to the existential minimum, which are pre-legal and inherent to human dignity (GLOECKNER, 2013). The principle of reserve for contingencies, which originated in Germany, discusses the idea of social claims being limited by what the state can reasonably fulfill (SILVA, 2015; MÂNICA, 2007). On the other hand, the reserve of consistency pertains to the transparency of a judge's reasoning in decision-making processes that involve conflicting constitutional rights (PEREIRA JUNIOR, 2014).

The principle of proportionality sets boundaries for a right when fundamental rights conflict, guided by the precepts of adequacy, necessity, and strict proportionality (SILVA, 2015). CF/88 acknowledges the interdependence of social and economic policies in securing the right to health (BRASIL, 1988). Public administration is governed by constitutional principles such as legality, impersonality, morality, and publicity (BRASIL, 1988), mandating ethical and transparent conduct from public agents (MAZZA, 2014). Constitutional Amendment No. 19/1998 introduced the principle of efficiency to public administration, aiming to optimize resource use and enhance service quality (ALCANTARA, 2009).

ETHICAL CONDUCTS AND HEALTHCARE STANDARDS

Ethics refers to the systematic recognition of respectability and its demands on human beings (RACHELS, RACHELS, 2015), while morality encompasses conduct precepts generated by

a specific society (KIENEN, 2017). Beauchamp and Childress's principled ethics approach identifies four ethical principles for medical practice: autonomy, non-maleficence, beneficence, and justice, which are not hierarchical or absolute (BUB, 2005). In case of conflict, situation analysis determines which principle takes precedence.

Healthcare professionals, as public agents, must adhere to the principles of legality, morality, and impersonality, which encompass the concepts of ethics and morality, as they deal with human beings with their own ideologies (KIENEN, 2017). The National Health Council, through Resolution No. 466 of December 12, 2012, sanctioned directives and regulatory precepts for research involving human beings, incorporating bioethical referential principles such as autonomy, non-maleficence, beneficence, justice, and equity, among others, aiming to ensure the rights and duties of research participants, the scientific community, and the state (BRASIL, 2012a).

Although the principled ethics approach is not unanimously accepted, these principles can be taken as a first step in establishing valid strategies to change the dominant modus operandi in healthcare. Nevertheless, no ethical standard is absolute in healthcare ethics (BUB, 2005), and other concepts should be considered in situations of conflict.

COMPLIANCE PROGRAMS

Compliance refers to the adherence to legal requirements, ethical behavior, and conventional conduct standards (XAVIER, 2020). It involves rigorous implementation of actions within or outside a company, covering ethical and moral principles. The compliance process directs people's conduct, providing practical guidance to benefit the community (GIOVANINI, 2014). In this context, a compliance program aims to ensure that all individuals associated with a company follow its business practices, which should be guided by established behavioral and action guidelines, specifically targeting the fight against corruption (UBALDO, 2017).

According to Act nº. 8,420 of 2015, the integrity program comprises a series of internal mechanisms aimed at implementing ethical guidelines and efficient behavior. This program should be designed, practiced, and updated according to each company's specific qualities and risks, ensuring its effectiveness and adaptability (BRASIL, 2015). Compliance transcends legal matters, encompassing governance, ethics, public and private management, risk management, and auditing (NEVES, 2018).

Corruption is a global phenomenon that undermines democratic institutions, hinders economic progress, contributes to political instability, and exacerbates social inequality (GOMES, 2021). In Brazil, corruption can manifest through a culture, in which individuals evade rules, laws, or bureaucratic procedures to obtain personal benefits (BRAUN, 2014). This

corruption culture perpetuates itself due to the passive acceptance of these actions across various spheres and environments (GIACOBBO, NOTARI, 2014).

International legislative processes have sought to regulate markets and prevent corrupt acts in response to the global and contagious nature of corruption (FRATTON, 2014). In Brazil, the legislative notoriety of compliance began with Resolution 2554 of the Central Bank in 1998. The approval of Law 12.846/2013 encouraged the creation and implementation of compliance programs aimed at preventing or reducing risks and ensuring adherence to prescribed rules (SCHRAMM, 2018).

Compliance goes beyond merely monitoring and controlling organizations; it is part of an affirmative action proposal aimed at strengthening transparency and legitimacy within corporate structures, thereby enhancing the application of ethical conduct and adherence to legal regulations (ALENCAR, 2019). Transparent business contexts hinder deviations and facilitate the detection of irregularities. From this perspective, implementing a compliance program is well-received in order to fight corruption, particularly in public procurement and contracts (XAVIER, 2020).

The essential elements or steps in implementing a compliance program include commitment and participation from risk assessment and top management; as well as the establishment of an ethical behavior code focused on professionals working in sensitive areas. In addition to it, there's the need of continuous communication and training; whistleblowing channels, internal audits, and due diligence; and periodic process reviews (GIOVANINI, 2014; GOMES, 2021). These are also known as the five pillars: (1) Commitment and support from top management; (2) Body responsible for the Integrity Program; (3) Risk profile and analysis; (4) Structure of rules and instruments; and (5) Continuous monitoring strategies (GORGA, 2016).

COMPLIANCE IN HEALTHCARE

Compliance in the healthcare sector is often overlooked in Brazil and abroad, with many believing it only applies to large international corporations (SILVA, 2021). However, hospitals and clinics are subject to anti-corruption legislation, and their risk management can involve a compliance program (SILVA, 2021; GORGA, 2016). These anti-corruption regulations aim to hold legal entities accountable and establish limits on the assignment of responsibility for events (GORGA, 2016). Legal entities can be held objectively liable under Article 2 of Law No. 12.846 for illegal acts committed (BRASIL, 2013).

The implementation of integrity projects in healthcare institutions aims to prevent infractions, mitigate risks, and apply corrective measures (SILVA, 2021). Key elements of healthcare compliance include open communication, informed consent, the confidentiality of

patient data, controlled substances and materials, standardized processes, and professional development (GORGA, 2016).

This study analyzes the application of compliance in healthcare environments, focusing on the protection of patient data under the General Data Protection Law (LGPD) (BRASIL, 2018). The LGPD, enacted in 2018 and effective since September 2020, aims to protect citizens' fundamental rights of freedom, privacy, and the development of their personality (MPF, 2022). It applies to the processing of personal data of any individual in Brazil, regardless of the data center's location (BRASIL, 2020).

The LGPD regulates the collection and processing of personal data, including sensitive data and data related to children and teenagers (BRASIL, 2020). Consent is a crucial element when dealing with sensitive data, and parental or legal guardian consent is required for minors (BRASIL, 2018). The law grants individuals' various rights, including the ability to request the deletion of their data, revoke consent, and transfer data to another service provider (MPF, 2022).

The National Data Protection Authority (ANPD) was established to enforce, regulate, and supervise the LGPD, and to impose sanctions when necessary (SERPRO, 2022a). Penalties for non-compliance can include fines of up to 2% of a company's annual revenue, capped at BRL 50 million per infraction (SERPRO, 2022a).

DATA TREATMENT AND COMPLIANCE IN HEALTHCARE

Healthcare is perhaps the subject that deals most with sensitive data, as defined by Brazilian legislation (PINHEIRO, 2019). Consequently, experts have debated the inclusion of data protection in the Constitution (SERPRO, 2019). Although health-related data is not explicitly mentioned, Constitutional Amendment No. 115/22 implicitly protects personal data as a fundamental right (BRASIL, 2022). However, a 2019 Serasa Experian⁵ study revealed that only 8.7% of healthcare companies comply with the General Data Protection Law (LGPD), highlighting the need for stronger information security practices in the healthcare sector (PINHEIRO, 2019).

Two publicized cases of healthcare professionals' misconduct involving the disclosure of patients' confidential data serve as examples. The first, predating the LGPD's approval in 2017, involved a rheumatologist who shared the diagnosis and health status of former First Lady Marisa Letícia with ex-colleagues on a messaging application (BAIBICH, 2017). The hospital

⁵ SERASA is a Brazilian credit research firm. It maintains credit histories, helping businesses manage risk and prevent fraud while aiding in credit decisions.

subsequently dismissed the professional, and the Medical Council investigated any potential breaches of the Code of Medical Ethics (CEM). The second, more recent case involved the disclosure of actress Klara Castanho's medical record by a nurse, who may face criminal charges and ethical code violations as a result of the LGPD's approval (VAZAMENTO..., 2022).

Both cases involve violations of fundamental rights, such as privacy and freedom, protected under the Federal Constitution of 1988 (CF/88) and the LGPD. The CEM also obliges medical professionals to maintain confidentiality regarding information obtained in their professional capacity (CFM, 2019). These cases demonstrate the need to extend responsibility for confidentiality to all healthcare institution staff, including nurses.

Moreover, these incidents highlight the importance of updating hospital ethical codes to prevent inappropriate data handling by professionals. Institutions must urgently adapt to the LGPD, as non-compliance constitutes a breach of both a fundamental right and federal law. The hospital where Klara Castanho was treated is one such example (DUTRA, 2022). The Anti-Corruption Law also states that both individuals and legal entities may be held liable for illegal acts (GOMES, 2022).

The implementation of a compliance program in healthcare institutions can detect non-conformity, enabling corrective measures and accountability (DUTRA, 2022). Both the individuals involved in the cases above were dismissed as punishment for their misconduct. Compliance programs and LGPD regulations intersect to protect sensitive personal data (DUTRA, 2022). Therefore, healthcare institutions must urgently implement compliance or integrity programs to mitigate potential risks and avoid market value, reputation, or financial damages caused by employees' misconduct concerning patient data handling (PINHEIRO, 2019).

THE ANTI-CORRUPTION LAW AND THE HEALTHCARE SECTOR

The Brazilian Anti-Corruption Law, along with the new Federal Act Nº 11.129/2022, holds significant importance for companies operating in the healthcare sector. As healthcare is a sensitive sector, with potential impacts on public health and safety, ethical and compliance issues are critical. Companies are prohibited from engaging in corrupt practices, such as bribery of public officials and politicians, and are strictly liable for any acts of corruption committed by their employees, agents, or third-party partners (BUAIZ NETO et al, 2022).

The law requires that companies implement effective compliance programs to detect, prevent, and repair corrupt practices. The new decree reinforces the importance of such programs in healthcare, outlining elements such as risk assessments, internal controls, training, and monitoring. It also offers leniency agreements for companies with effective compliance

programs, reducing or even eliminating administrative penalties. Companies operating in the healthcare industry must ensure they have effective compliance programs to mitigate legal and reputational risks (BUAIZ NETO et al, 2022; NISHIJIMA, ELLIS, CATI, 2022; RICHARD, 2014).

DISCUSSIONS AND CONSIDERATIONS

This article encountered limitations due to the recency of the LGPD and health institutions not yet understanding the need to implement an Integrity Program and ensure security for the patients' data.

However, from the analysis developed, it was possible to observe how the right to access health in Brazil has been neglected over the years, only becoming positively recognized in the late 20th century, after popular movements that began in the 1970s due to public health problems and economic crises. This expanded the fight for the right to health, which was no longer restricted to formal workers and was granted to all Brazilian citizens by the 1988 Constitution.

The effecting of the social right to health occurred with the creation of the world's largest public health system, SUS, aimed at promoting social justice by providing care to everyone. Thus, the right to health, like other social rights that are constitutional mandates, seeks to equalize unequal social conditions, allowing less privileged Brazilians to have a better quality of life.

It is relevant to distinguish between ethics and morality when dealing with ethical conduct, as ethics result from personal critical judgment, while morality consists of social conduct norms generated by a particular society. Ethics, therefore, is an individual posture based on moral principles. When applied to the conduct of health professionals, their *modus operandi* must be guided by the commitment to always act in the best interest of the patient's health, showing solidarity and responsibility, and not considering financial matters in healthcare, thus respecting the rights of others.

Since no ethical standard is absolute when it comes to ethics in health, if there is a situation of ethical conflicts in healthcare routines, other concepts such as tolerance, equity, solidarity, and responsibility should be considered. In everyday practice, the relationship between users and healthcare professionals should be balanced to ensure the right to health.

In healthcare's ethical management, the primary concern should be privacy, security, and confidentiality of confidential information and sensitive data. Given the increasing virtualization of data, greater care must be taken with information obtained from consultations, records, internal processes and procedures, tests, documentation, and others, maintaining the

highest standard of patient data confidentiality, especially from unauthorized personnel.

Regarding compliance programs, they are proposed as a practical application of ethical conduct and greater adherence to legal regulations, as their supporting pillars are ethics, morality, and law. Thus, the program must ensure, through administrative, technical, and physical support, that data remains safe, accurate, complete, and integral, maintaining the highest level of confidentiality.

In healthcare, companies must promote integrity programs and policies for sectors lacking ethical principles and should not engage in or tolerate harmful activities. They must also establish guidelines to detect irregularities, misconduct, and illicit acts. The company should not allow its image to be damaged and must mitigate any chances of this happening through the compliance program.

With virtualization, the need for specific legislation to protect virtual and informational privacy became essential, which is the purpose of the General Data Protection Law (LGPD). Thus, its goal is an important aspect of safeguarding fundamental rights to freedom and privacy, and data protection constitutes one of its main benefits.

The greater gain was established by raising data protection to a fundamental right, guaranteed by the 1988 Constitution, as it is elevated to a normative category superior to Brazilian legal norms, which can apply restrictive sanctions to protect this right and provide support for the LGPD's reinforcement and implementation.

Health institutions must implement a compliance or integrity program to mitigate risks and avoid damage due to employee misconduct regarding the treatment of patient data. It is undeniable that healthcare professionals' attitudes should be guided by ethical and moral standards when dealing with personal data, especially patients' sensitive data.

In conclusion, this study found that the proposed objectives were achieved, and the guiding question: "from the perspective of LGPD's legal parameters, what are the implications and advantages of adopting compliance programs for healthcare professionals and institutions and for patients?" served as a guide for the entire research undertaken.

As it is not possible to encompass all possibilities that the topic provides, and it would be overly ambitious to explore it in a single monograph; future studies could involve field research with healthcare professionals, managers, and users of the health system in companies that adopt integrity programs, focusing on their perceptions of the advantages of compliance adoption. Another suggestion would be the research on the implications of LGPD implementation in healthcare institutions. These are also recent topics in healthcare that deserve further study.

By researching and understanding the implications of adopting compliance programs

and the LGPD, healthcare professionals, institutions, and patients can better navigate the complex landscape of data protection and privacy in the digital age. The adoption of such programs and adherence to the LGPD will not only help maintain the trust between healthcare providers and patients but will also ensure that the fundamental right to privacy is upheld and respected in the healthcare sector.

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