



## International and National Legal Frameworks for Corporate Governance in Healthcare

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### ABSTRACT

The history of corporate governance reflects what it stands for- the principles and practices that ensure transparency, accountability, ethical decision-making, and stakeholder interests. This article aims to analyze the significance and development of corporate governance specifically in the healthcare industry. It navigates through the priorities of corporate governance and discusses the various legal frameworks, nationally and internationally, that aim at regulating corporate affairs in the health sector.

It is a comparative analysis between corporate governance policies of the past and the present, as well as between different nations. The Indian regulatory framework is a comprehensive one, albeit with wide scope for improvement, as compared to that of Canada where there is no uniform federal pressuring mechanism for the same.

The article finally highlights the need for more niche research and legislative and executive actions, along with an active role of the regulatory bodies and committees formed to ensure that corporate governance in healthcare does not remain a toothless tiger but actually drives medical corporations to comply with their duties of compliance.

### I. INTRODUCTION

The Chartered Governance Institute (UK and Ireland) defines 'Corporate Governance' as "the system of rules, practices and processes by which a company is directed and controlled."<sup>1</sup> Further, it calls it a "toolkit" that enables management and the

Board of Directors to deal with the various challenges that are incidental to the running of a company – such as determining who has power, accountability, and the authority to make decisions, etc.<sup>2</sup> It involves the commitment of a company to run its businesses in a legal, ethical and transparent manner - a dedication that must come from the very top and permeate throughout the organisation.<sup>3</sup>

Corporate governance is necessary to ensure the balance of interests of all stakeholders. The stakeholders in the healthcare corporate sector would include the investors and employees of the institution, the patients in a hospital and conversely, the customers at a pharmacy, the suppliers of medical equipment and medicinal drugs, the government, and the society as a whole. Corporate governance not only handles the internal management with a profit-motive but also includes the processes through which a company sets and pursues its objectives in the wider context of a social, regulatory and market environment,<sup>4</sup> all along ensuring the stakeholders of their trust in the company's operations.

The healthcare industry is one of the foundational pillars of society, as it deals with none other than human life itself, providing medical services for public welfare. A developed healthcare industry is a hallmark for a developed nation, and a bulwark against even the worst form of pestilence.

The seeds of corporate governance were planted in ancient civilizations like ancient Greece and Rome, where city-states and merchant guilds established codes of conduct and governance principles to regulate commercial activities.<sup>5</sup> In a

<sup>1</sup> *What is corporate governance?*, CHARTERED GOVERNANCE INSTITUTE UK & IRELAND (March 15, 2024, 6:33 PM), [www.cgi.org.uk/about-us/policy/what-is-corporate-governance#:~:text=Corporate%20governance%20is%20the%20system,accountability%2C%20and%20who%20makes%20decisions.](http://www.cgi.org.uk/about-us/policy/what-is-corporate-governance#:~:text=Corporate%20governance%20is%20the%20system,accountability%2C%20and%20who%20makes%20decisions.)

<sup>2</sup> *Id.*

<sup>3</sup> CII Task Force, *Corporate Governance: Recommendations for Voluntary Adoption* (Issued in November 2009).

<sup>4</sup> *Supra note 1.*

<sup>5</sup> Arnab Paul, *Transforming Healthcare through Effective Corporate Governance*, LINKEDIN (March 15, 2024, 6:38 PM), [www.linkedin.com/pulse/transforming-](http://www.linkedin.com/pulse/transforming-)



more recent set-up, the Cadbury Committee's Code of Best Practice, 1992 in the UK and the Sarbanes-Oxley Act of 2002 in the USA can be accredited for giving momentum to the tide of corporate governance. The Cadbury Report recommended transparent financial reporting, independent audit committees, and giving the positions of CEO and Chairman to separate people.<sup>6</sup> The SOX Act on the other hand focussed more on investor-interests and introduced disclosure requirement, stringent reporting and further enhanced the independence of auditors.<sup>7</sup> The OECD Principles, 1999 (revised in 2023) give a comprehensive framework for good governance practices as well.<sup>8</sup>

#### CORPORATE GOVERNANCE IN HEALTHCARE

Healthcare institutions, just like any other body corporate, face issues relating to governance as well –the usual challenges such as regulatory compliance, ethical decision-making, and financial sustainability as well as some challenges that are hyperspecific to the field, such as patient safety, quality of care, and a stakeholder-centric approach.<sup>9</sup> Corporate governance in the healthcare sector simply means emphasising upon transparency, accountability, strict-costing measures, quality healthcare, and patient-care, along with bringing in the latest technology to benefit patients and being self-sufficient.<sup>10</sup>

The shift of primary focus in corporate governance towards a stakeholder-centric and a patient-centric governance is one of the most significant trends. Apart from that, values such as transparency and ease of accessibility to information for the stakeholders have become more solidified. Additionally, the intersection of corporate governance with technology has given birth to a higher level of efficiency with advancements such as electronic health records, telemedicine, and data

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<sup>6</sup> Jay Dahya et al., *The Cadbury Committee, Corporate Performance, and Top Management Turnover*, 57 THE JOURNAL OF FINANCE 461, 461 (2002).

<sup>7</sup> The Sarbanes-Oxley Act, 43 U.S.C (2002).

<sup>8</sup> OECD, *G20/OECD Principles of Corporate Governance*, OECD PUBLISHING: PARIS (2015).

<sup>9</sup> 57 THE JOURNAL OF FINANCE, *supra* note 5.

<sup>10</sup> Rajesh Kumar, *Corporate Governance in Health Care Sector in India*, 11 JOURNAL OF ADVANCES AND SCHOLARLY RESEARCHES IN ALLIED EDUCATION 1, 1 (2016).

analytics<sup>11</sup> at the beck and call of healthcare institutions.

In India, the healthcare industry is one of the fastest-growing sectors, with a projected compound annual growth rate of 22.87% between 2020 and 2025.<sup>12</sup> There was also a boom in medical tourism in India in the past decade, which had acted as a catalyst to the concept of corporate governance in India.<sup>13</sup> Naturally, it is also highly regulated using corporate governance that ensures that companies and health institutions adhere to the highest ethical and professional standards.

One of the most basic grundnorms for corporate governance, not only in the healthcare sector but for companies in general can be derived from the Companies Act, 2013<sup>14</sup> that requires all companies to establish a Board of Directors, an audit committee, and a nomination and remuneration committee,<sup>15</sup> and to comply with its corporate social responsibility. The social responsibility of healthcare institutions was also emphasized upon by the International Bioethics Committee of UNESCO in its report titled 'Social Responsibility and Health' published in 2010.<sup>16</sup>

#### NATIONAL LEGAL FRAMEWORK FOR CORPORATE GOVERNANCE IN HEALTHCARE

The legal and regulatory framework in India for corporate governance in the healthcare industry derives itself from various Acts and Guidelines. Despite extensive legislative measures, the practicality seen in real-life situations tells a different story. There is deep-rooted corruption embedded in the hearts of these institutions that poses a challenge to the values of transparency, accountability and patient-care quality.

<sup>11</sup> *Supra* note 5.

<sup>12</sup> Madhav M Singh, *Importance of Corporate Governance in the Healthcare Industry*, LINKEDIN (March 15, 2024, 6:45 PM), [www.linkedin.com/pulse/importance-corporate-governance-healthcare-industry-madhusudan-singh/](https://www.linkedin.com/pulse/importance-corporate-governance-healthcare-industry-madhusudan-singh/).

<sup>13</sup> *Id.*

<sup>14</sup> The Companies Act, 2013 (India).

<sup>15</sup> LINKEDIN, *supra* note 12.

<sup>16</sup> INTERNATIONAL BIOETHICS COMMITTEE, REPORT OF THE INTERNATIONAL BIOETHICS COMMITTEE OF UNESCO (IBC) ON SOCIAL RESPONSIBILITY AND HEALTH, 5 (UNESCO 2010).



- **The Ministry of Health and Family Welfare**

The Ministry itself assumes a regulatory role. The National Health Policy of India, 2017 provided in its Section 14 that the regulatory role of the Ministry of Health and Family Welfare includes “regulation of clinical establishments, professional and technical education, food safety, medical technologies, medical products, clinical trials, research and implementation of other health related laws”.<sup>17</sup> It stated that this regulatory role will entail moving towards a “more effective, rational, transparent and consistent regime.”<sup>18</sup>

- **Clinical Establishments Act, 2010**

The National Health Policy, 2017 also talks about regulation of clinical establishments, stating that a few States have already adopted the Clinical Establishments Act, 2010, and there would be advocacy with other States to urge them to adopt the Act as well, which lays emphasis on points such as-

- Grading of clinical establishments;
- Active promotion and adoption of standard treatment guidelines;
- Protection of patient rights in clinical establishments (such as rights to information, access to medical records and reports, informed consent, second opinion, confidentiality and privacy);
- Standard Regulatory framework for laboratories and imaging centers; and
- Creating specialized emerging services.<sup>19</sup>

The Policy also recommended setting up of a separate, empowered medical tribunal for speedy resolution of medical cases regarding standards of care, prices of services, negligence and unfair practices.<sup>20</sup>

- **Drug,<sup>21</sup> Medical Devices,<sup>22</sup> and Clinical Trial Regulation<sup>23</sup>**

An important aspect of corporate governance from the point of view of patient-centric care-giving mechanism is the regulation of the

above-mentioned. The Policy states that although the price and availability of drugs is regulated by the Department of Pharmaceuticals, it recommends streamlining the system of their procurement and creating a transparent drug-purchase policy for bulk purchases. Similarly, it encourages establishing a regulatory body for medical devices to promote innovation and entrepreneurial spirit for their manufacture. Further, it states that for the purpose of ensuring the rights, safety and well-being of clinical trial participants, regulation clauses should be included in the Drugs and Cosmetics Act. It also states that the Global Good Clinical Practice Guidelines, which specifies standards, roles and responsibilities of sponsors, investigators and participants should be adhered to.

- **Centre, State and Panchayati Raj Institutions**

The NHP in Section 26.1<sup>24</sup> and 26.2<sup>25</sup> respectively states that responsibility and accountability shall be divided between the Centre, State and Local governments for governance.

- **Accountability and Legal Framework under the NHP**

Sections 26.3 and 27 of the NHP lay down the increased horizontal and vertical accountability of the health system with the help of local bodies, community monitoring<sup>26</sup> etc. as well as support the need for moving towards a rights-based approach to healthcare while remaining conscious of the fact that threshold levels of finances and infrastructure is a precondition for an enabling environment, to ensure that the poorest of the poor stand to gain the maximum.<sup>27</sup>

- **The Indian Council Medical Research**

The ICMR releases various guidelines that provide regulation for different aspects of corporate governance, such as its reports on:

- ‘Code of Conduct for Scientists’<sup>28</sup>: that lays down some basic principles to be followed as autonomy, beneficence, non-maleficence, risk minimization, confidentiality, ethical review, compliance, research integrity, and justice, etc.;

<sup>17</sup> Ministry of Health and Welfare: Government of India, National Health Policy, 14 (2017).

<sup>18</sup> *Id.*

<sup>19</sup> *Id.* at 14.2.

<sup>20</sup> *Id.*

<sup>21</sup> *Id.* at 14.4.

<sup>22</sup> *Id.* at 14.5.

<sup>23</sup> *Id.* at 14.6.

<sup>24</sup> *Id.* at 26.1.

<sup>25</sup> *Id.* at 26.2.

<sup>26</sup> *Id.* at 26.3.

<sup>27</sup> *Id.* at 27.

<sup>28</sup> Indian Council of Medical Research, Guidelines on Code of Conduct for Research Scientists engaged in field of Life Sciences (2019).



→ ‘Condemnation’<sup>29</sup>: that gives guidelines on disposal of goods and its various modes;

→ ‘Utilization of Corporate Social Responsibility Funds’<sup>30</sup>: that is to ensure effective utilization of funds generated from a donation to help develop diagnostics, therapeutics, vaccines and devices whilst carrying out Sustainable Development Goals and promoting ‘Make in India’; and

→ Multiple guidelines on Ethical Requirements and Conduct.<sup>31</sup>

#### ● **Food Safety and Standards Act, 2006**

The NHP also threw light upon the importance of establishing and strengthening a necessary network of offices, laboratories, e-governance structures and human resources needed for the enforcement of the FSS Act, 2006.<sup>32</sup> This Act was meant to consolidate the existing food laws and establish a regulatory framework to promote health and tackle the problems of food adulteration and contamination that adversely affect consumer health and trust.<sup>33</sup>

#### ● **Good Clinical Practice Guidelines, India**

A set of guidelines for biomedical studies was issued which encompassed the design, conduct, termination, audit, analysis, reporting and documentation of the studies involving human subjects.<sup>34</sup> It aimed to ensure the ethical and scientific soundness of the studies. The guidelines established two cardinal principles for corporate governance in healthcare: protection of the rights of human subjects and authenticity of biomedical data generated.<sup>35</sup> It included pre-requisites such as:

→ Assessment of safety<sup>36</sup>

→ Quality control and quality assurance<sup>37</sup>

→ Finance and insurance<sup>38</sup>

→ Ethical & Safety Considerations, including the principles of privacy and confidentiality, non-exploitation, accountability and transparency, professional competence, inter alia.<sup>39</sup>

It also gave for the composition of an Ethics Committee<sup>40</sup> and lays down responsibilities<sup>41</sup> for various authorities.

#### **INTERNATIONAL LEGAL FRAMEWORK FOR CORPORATE GOVERNANCE IN HEALTHCARE**

There are various regulatory frameworks that are native to other nations. Apart from various national frameworks, there are also some international guidelines for good governance of the healthcare industry.

#### ● **Guideline for Good Clinical Practice, ICH Harmonised Guideline<sup>42</sup>**

These guidelines provide for the authorities of Investigator and Sponsor and lay down their various responsibilities such as medical care of test subjects, compliance with protocol, safety reporting, progress reports and final report by the Investigator<sup>43</sup>, along with, quality management, assurance and control, medical expertise, financing, allocation of responsibilities, record access, monitoring, audit, noncompliance, etc. to be handled by the Sponsor.<sup>44</sup> It also amended the Clinical Trial Protocol<sup>45</sup> and also composed an Institutional Review Board (IRB) or an Independent Ethics Committee (IEC).<sup>46</sup>

#### ● **Various Foreign Legal Frameworks**

##### **USA**

The Sarbanes-Oxley Act was perhaps the most significant legislative moment in the United

<sup>29</sup> Indian Council of Medical Research, Guidelines for Condemnation (2019).

<sup>30</sup> Indian Council of Medical Research, Guidelines for Utilization of Corporate Social Responsibility Funds (August, 2023).

<sup>31</sup> *Guidelines*, ICMR (March 15, 2024 8:50 PM), <https://main.icmr.nic.in/content/guidelines-0>.

<sup>32</sup> Ministry of Health and Welfare: Government of India, National Health Policy, 14.3 (2017).

<sup>33</sup> Food Safety and Standards Act, 2006 (India).

<sup>34</sup> Central Drugs Standard Control Organisation, *Good Clinical Practice Guidelines*, 2003, MINISTRY OF HEALTH AND WELFARE 1, 1 (March 15, 2024, 9:15 PM), <https://rgcb.res.in/documents/Good-Clinical-Practice-Guideline.pdf>.

<sup>35</sup> *Id.*

<sup>36</sup> *Id.* at 2.3.1.8.

<sup>37</sup> *Id.* at 2.3.1.11.

<sup>38</sup> *Id.* at 2.3.1.12.

<sup>39</sup> *Id.* at 2.4.

<sup>40</sup> *Id.* at 2.4.2.

<sup>41</sup> *Id.* at 3.1-3.3.

<sup>42</sup> ICH, Guideline For Good Clinical Practice, E6 (R2) (Issued on November 9, 2016).

<sup>43</sup> *Id.* at 4.

<sup>44</sup> *Id.* at 5.

<sup>45</sup> *Id.* at 6.

<sup>46</sup> *Id.* at 3.



States pertaining to corporate governance in the healthcare sector. The implications it had for private and non-profit health organisations included introducing the concepts of corporate accountability, the Board's duty of oversight, disclosure and control procedures, Audit Committee oversights, whistleblower protection, corporate and criminal fraud accountability, amongst many more.<sup>47</sup> Apart from that the Patient Protection and Affordable Care Act (ACA), widely referred to as 'Obamacare' brought significant changes in the US healthcare system as well, bringing about insurance reforms and an increased demand for services.<sup>48</sup> The Centers for Medicare and Medicaid Services (CMS) promulgates most laws at the federal level.

#### Canada

There are various regional boards across Canada that handle corporate governance for hospitals or a region of hospitals. According to a study conducted around three Canadian Boards and an American Board, it was found that some boards believe that the Medical Advisory Committee is responsible for quality assurance and governance. Some believe that the public sector does not put pressure on healthcare organisations for proper compliance to good governance therefore Accreditation Canada Standards are followed by them. Further, the Saskatoon Health region uses two dashboards, one developed by the Ministry of Health that includes financial and access measures and one produced internally that focuses more on quality and safety.<sup>49</sup>

#### • Other Countries

Northern Ireland: The Public Health Agency, established by the Health & Social Care (Reform) Act (Northern Ireland), 2009 gives the official legal framework on corporate governance.<sup>50</sup>

Kazakhstan: The Ministry of Health's 'Development of Management and Corporate Governance in Healthcare Organizations' project gives its corporate governance framework.<sup>51</sup>

Egypt: The Center for International Private Enterprise gave Principles & Guidelines for Governance in Hospitals, 2014 as a guiding mechanism.<sup>52</sup>

Netherlands: The Dutch Healthcare Authority, the Healthcare Market Regulation Act, and the guidelines issued by the Authority for Consumers and Markets is their framework on corporate governance.<sup>53</sup>

## II. CONCLUSION

There are still many countries that do not have a comprehensive corporate governance framework that would be uniform while also retaining a close grasp on all institutions, maintaining compliance and regulation, such as Lebanon where there has been no systematic investigation of corporate governance practices in the healthcare sector.<sup>54</sup>

The Indian government on the other hand has introduced various guidelines and regulatory framework mechanisms to promote compliance by companies to the values laid down under corporate

<sup>47</sup> Frank Sheeder, *Corporate Governance and Compliance for Health Care: A Practical Guide*, WOLTERS KLUWER (March 16, 2024, 12:39 PM), <https://law-store.wolterskluwer.com/s/product/corporate-governance-for-health-care-vitallaw-3r/01tG000000Lu0NYIAZ>.

<sup>48</sup> Foley & Lardner LLP, *In Review: The Healthcare Framework in USA*, LEXOLOGY (March 16, 2024, 12:43 PM), <https://www.lexology.com/library/detail.aspx?g=f454e57d-6b23-4fb6-94a1-18451573ac99>.

<sup>49</sup> G. Ross Baker et al., *Designing Effective Governance for Quality and Safety in Canadian Healthcare*, SPRINGER (March 16, 12:55 PM), <https://link.springer.com/article/10.1186/s12913-019-4593-0#ref-CR10>.

<sup>50</sup> Public Health Agency, *Corporate Governance Framework*, 1.2 (Issued in August 2014).

<sup>51</sup> I.S. Saktaganova et al., *Legal Framework of Developing Corporate Governance in Healthcare Organizations in Kazakhstan*, X JOURNAL OF ADVANCED RESEARCH IN LAW AND ECONOMICS 890 (2019).

<sup>52</sup> The Center for International Private Enterprise, *Principles & Guidelines for Governance in Hospitals, Egypt 2014*, HGTA (March 16, 2024, 1:08 PM), [http://undp-aci.org/publications/Principles\\_and\\_Guidelines\\_for\\_Governance\\_in\\_Hospitals\\_EN.pdf](http://undp-aci.org/publications/Principles_and_Guidelines_for_Governance_in_Hospitals_EN.pdf).

<sup>53</sup> *Good Governance in the Care Sector*, GOVERNMENT OF THE NETHERLANDS (March 16, 2024, 1:12 PM), [www.government.nl/topics/quality-of-healthcare/good-governance-in-the-care-sector](http://www.government.nl/topics/quality-of-healthcare/good-governance-in-the-care-sector).

<sup>54</sup> Dima Jamali et al., *Corporate Governance and Corporate Social Responsibility: Evidence from the Healthcare Sector*, 10 EMERALD GROUP PUBLISHING 590 (2010).



governance. The Indian regulatory framework is designed to navigate the challenges that are unique and specific to the Indian healthcare industry, such as shortage of healthcare professionals, inadequate infrastructure, and lack of funding etc.<sup>55</sup>

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<sup>55</sup> LINKEDIN, *supra* note 12.