



**Legal Aspects in Healthcare
Management:
A Compilation of Relevant
Acts and Legislations**

LIST OF ABBREVIATIONS

A/C: Air Conditioning	MBBS: Bachelor of Medicine and Bachelor of Surgery
AERB: Atomic Energy Registration Board	MCI: Medical Council of India
AIDS: Acquired Immuno-Deficiency Syndrome	MoHFW: Ministry of Health and Family Welfare
ANC: Ante Natal Care	MTP: Medical Termination of Pregnancy
ANM: Auxiliary Nurse and Midwifery	INC: Indian Nursing Council
CHC: Community Health Centre	NGO: Non Governmental Organization
CMLT: Certificate in Medical Laboratory and Technology	NS: Normal Saline
CPCB: Central Pollution Control Board	OPD: Out Patient Department
DCI: Dental Council of India	OT: Operation Theatre
DGHS: Director General of Health Services	PAN: Permanent Account Number
DMLT: Diploma in Medical Laboratory and Technology	PBA: Payment of Bonus Act
EPF: Employee Provident Fund	PCPNDT: Pre Conception Pre Natal Diagnostic Test
FDA: Food and Drug Authority	PER: Protein Energy Ratio
GOI: Government of India	PG: Post Graduate
HIV: Human Immunodeficiency Virus	PGA: Payment of Gratuity Act
ICU: Intensive Care Unit	PHC: Primary Health Centre
IEC: Information Education Communication	PLWHIV: People Living with HIV
IHR: International Health Regulations	PNC: Post Natal Care
INR: Indian National Rupee	PPP: Public Private Partnership
IPD: In Patient Department	ROC: Registrar of Companies
IT: Information Technology	RTO: Road Transport Officer
IV: Intra Venous	SC: Sub Centre
LSA: Local Supervisory Authority	US: United States
USG: Ultra-Sono-Graphy	
UT: Union Territory	
WHO: World Health Organization	

FROM THE EDITOR'S DESK

Healthcare is an essential commodity. Rapidly changing demographic trends, spiraling population base, increasing affordability with rising income, have further contributed to the escalation in the need, for “good quality” healthcare. Reports suggest that private sector dominates the healthcare delivery market due to their ubiquitous presence and growing inadequacies in the public sector. The Ernst and Young Report projects a need for 10 lakh hospital beds in the next five years, and anticipates that 88% of this will come from the private sector.

Understanding Law and Legal framework of the constitution is imperative for any form of business or activity, including healthcare. Unfortunately, most of this information is scattered across various Acts and Statues. To add to this, legal language is very technical and difficult to be interpreted by a non-legal person. Inevitably, except for a select few, the healthcare segment is largely oblivious and unaware of the various legalities governing it.

This compilation is an effort to bridge the existing gap and providing the reader with all the relevant and latest information related to or affecting the healthcare segment. The compilation brings together various Acts and Regulations, essential to be understood by the healthcare segment. Further, the compilation presents common laws in relevance to healthcare, to make it more reader-friendly and simplify contextualization.

The laws have been presented in simple, ease and comprehensible formats for the benefit of the reader. Unlike other compilations, this compilation attempts to provide the interpretation of the Acts, so as to enhance its utility for the target readers. Further, much given in the Legislations is of little utility to the reader, which has been rationally screened out.

HOSMAC Foundation is a NGO dedicated towards promoting education and research in healthcare. In lieu of its objective, the Foundation is actively involved in dissemination information and developing useful databank for the benefit of the healthcare community. In furtherance to this objective, the Foundation has initiated publications, which it presumes will vigorously contribute to the knowledge base of the readers within and outside the healthcare community.

All necessary measures have been taken to ensure that this publication is comprehensive and exhaustive, to serve the objective mentioned herewith. Yet, we realized that omissions might have taken place and so we welcome any suggestions or criticism, related to this publication. We look forward to your extended support to improve the quality and utility of this document.

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PREFACE

Though seemingly unrelated, medicine and law have a long association. Law enforcements agencies seek medical assistance all the time. Like every human activity, health care also needs to be regulated. Some kind of guidelines to practice medicine existed for thousands of years. Hippocrates oath and the ethical principles in Ayurveda are some examples.

In modern times, legal provisions related to health care can be found in different statutes. Indian Penal Code, Environmental Protection Act, Epidemic Disease Control Act are more than centuries old. Laws are dynamic. They reflect the societal attitude at a particular period. It is worth noting that laws are enacted to control the behaviour and practice of certain section of the society. Recent examples are enactment of Human Organ Transplant Act to prevent commercialization in Kidney Transplants, PCPNDT Act to curb Female Feticide and Biomedical Waste Rules to stop spread of diseases due to infectious waste.

Till mid-eighties, though laws existed, medical and health care professionals, paid little attention to them. Application of Consumer Protection Act, 1984, to the doctors and health care institutions suddenly changed the perspective. Practically, every stake holder realized the importance of laws. The next two decades saw umpteen number of cases filed against health care providers and institutions. It resulted in enormous financial loss and damage to the reputation of individuals and institutions. It became imperative to know the laws to prevent complaints and legal cases. Everyone realized that it was prudent to remain on the right side of law.

In this scenario, a frequently asked question is “Where can I get a book which enumerates all the important laws applicable in a simple way?”

Unfortunately, with some exceptions, most of the applicable laws are scattered in several Acts. Further, the legal language is complex and not easily understood by lay persons.

There was a void in this area. I am extremely happy that HOSMAC Foundation has come up with this excellent publication “Legal Aspects in Health Care: A Compilation of Relevant Acts for Hospitals and Health Care Institutions” which attempts to fill this long felt vacuum to a large extent. It explains in a simple way the complex laws, which will be a boon to all the stake-holders.

I compliment and congratulate Dr. Vivek Desai, Managing Director, Hosmac India Ltd and Dr. Utkarsh Shah, Manager- Operations, HOSMAC Foundation. I recommend this book to all the stake-holders.

I wish the publication all the success.

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HOSMAC Foundation Team

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PRELUDE

Healthcare Institutions involved in delivery of care, like hospitals, pathology and diagnostic centres, wellness centres, polyclinics, day care centres, etc require to be updated with the latest mandatory healthcare legislation. Healthcare delivery has been increasingly recognized as a business avenue and hence regulatory norms are constantly becoming stringent. In lieu of the changing perception about healthcare delivery and the emphasis on enhancing quality, it has become pertinent for hospital and healthcare managers to remain abreast of the policy norms that regulate delivery of care. This compilation is created specifically, with the intent to provide relevant, vital and complete information about the governing laws and regulations. There are certain regulations that are applicable across the country, while some of the Acts have limited regional coverage. Though variations are inevitable among different regional Acts the gist of these Acts, their applicability, salient features, etc have been consolidated and provided in this document.

Healthcare organizations can be incorporated as either for profit organization, under the Companies Act, 1956 or as charitable organization under a host of other Acts like Charitable and Religious Trust Act, 1920, Society Registration Act, 1860 or Indian Trusts Act, 1888. It is mandatory for all organizations to register the nature of business, working hours for employees, composition of the employees, etc under other Acts like Shop and Establishment Act(s), Nursing Home Registration Act(s) or Clinical Establishment Act(s). The Establishment of Medical Colleges Regulation, 1999, The Nursing Council Act, 1947, The Dentist Act, 1948, etc governs medical and paramedical education and the mandatory requirements for establishment of educational institutions.

There are some common laws, which are applicable to the healthcare segment. The Indian Penal Code has several provisions, applicable to medical and paramedical professionals. These provisions have been specified in this document. The Consumer Protection Act, 1984, protect the consumers from losses/damages due to negligence by the concerned professional/ institution, has also been specified herewith. Further the latest Information Technology Act, 2000 has its implications on the healthcare industry, in terms of the relevance of the information under the Indian Evidence Act, 1872. Common Human Resources Acts have also been specified in this document, in reference to the healthcare segment. Similarly, in recent past, outsourcing has gained substantial recognition and the various regulations governing outsourcing include the Indian Partnership Act, 1932 and The Contract Act, 1872. It is equally essential for the Principal Employer to be aware of other applicable Acts like the Minimum Wages Act, 1948 and Workmen Compensation Act, 1923. A Contract document is a legal document and needs to be drafted with maximum clarity and should avoid any form of ambiguities. Basic and essential considerations while drafting a contract document include defining the scope of work, the terms and conditions for employees hired by the contract, payment schedules, deliverables and exit options for both the parties.

Hospitals and Healthcare institutions are multi-departmental organizations. Invariably, the general regulations governing healthcare institutions don't have adequate flexibility or are not as comprehensive in nature to address to specific departmental requirements. Hence a separate set of regulations have been designed for specific departments in hospitals and healthcare institutions. Some of the separate regulations

are meant for safe operations of X-ray and CT Scans, Biomedical Waste Management, Prevention of misuse of Ultrasound and Doppler Machines, Medical Termination of Pregnancy Act, 1971, Dispensing of Drugs, Organ Transplant, ensuring Food Safety, Registration of Ambulances and norms on Medical Tourism. Certain Acts like Professional Conduct, Etiquette and Ethics for Medical Professionals is meant to avert professionals for indulging in unethical practices and. It is essential for all healthcare organizations to be aware and thereby refrain from unethical practices and enforce quality.

Tax Laws governing healthcare institutions depend upon the incorporation of the organization. Charitable institutions can evade taxes if they utilize a stipulated amount of their income in charity, while for profit organization may be entitled to a 5 year tax holiday for developing infrastructure in rural India. Healthcare services are excluded by being taxed under the Service Tax regulations of the country.

Public Health Legislations are equally crucial for any healthcare institution or organization, as the overall mission of any healthcare institution is to promote good health. Inevitably it is essential to have an overarching understanding about some of the public health legislations being enforced in the country. The Epidemic Disease Act, 1889, The HIV/AIDS Bill, 2006, International Health Regulations, etc are some of the legislations covered herewith. Health information and statistics form a crucial part of the countries data bank and have vital legal implications. Health information is essential to rationalize the action of the policy makers and evaluate the progress of health interventions in the country. Registration of Births and Deaths and notification of endemic diseases is the responsibility of all healthcare institutions in the country.

This document provides insights into the various healthcare legislations pertaining to institutional set-ups along with an insight into public health regulations. The mandatory and optional registration details have been provided along with a brief of the various processes, responsibility of the concerned parties, etc. All efforts have been made to simplify the information and contribute effectively to the understanding of healthcare legislations.

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