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Helping India Comply

Simplifying Compliance Management

for Hospitals

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EXECUTIVE SUMMARY

This report examines the complexities and challenges of compliance management in Indian hospitals. It provides an in-depth analysis of the regulatory framework, types of healthcare institutions, and the compliance landscape, offering actionable recommendations to streamline processes and enhance regulatory adherence.

The Indian healthcare sector has seen remarkable growth, with public expenditure rising to 2.2% of GDP in FY23 from 1.6% in FY21. Valued at US$ 372 billion in 2023, the market is projected to reach US$ 638 billion by 2025. Key growth drivers include the burgeoning medical tourism market, valued at over $7 billion and expected to double by 2029, and the expanding e-health market, projected to reach US$ 10.6 billion by 2025. The sector employs 7.5 million people, and the integration of Artificial Intelligence (AI) is anticipated to create 3 million new jobs by 2028. Government support is significant, with a $10.93 billion allocation in the Interim Union Budget 2024-25 and a $6.8 billion credit incentive program to boost healthcare infrastructure.

The regulatory landscape for hospitals in India is complex, involving numerous central and state-level regulations. Key regulatory bodies include the National Accreditation Board for Hospitals & Healthcare Providers (NABH), the Central Drugs Standard Control Organisation (CDSCO), and the Atomic Energy Regulatory Board (AERB). Hospitals must comply with regulations covering patient rights, infection control, record maintenance, professional training, and various acts like the Drugs and Cosmetics Act, Telemedicine Practice Guidelines, and the New Drugs and Clinical Trials Rules.

Hospitals must navigate a labyrinth of 37 one-time registrations and approvals and numerous ongoing compliances across seven categories: Labour, Finance & Taxation, Environment Health & Safety (EHS), Secretarial, Commercial, Industry-Specific, and General. Further compliance requirements include over 100 certificates, licenses, permissions, and approvals under various acts. Fire Safety compliances are also an important concern for hospitals and require adherence to National Building Code (NBC) standards and NABH recommendations.

Hospitals face a wide range of challenges in their compliance functions, including:

- **Lack of Accurate Compliance Lists:** Managing 623 unique compliances for a single 50-bed hospital.
- **Fluid Regulatory Environment:** Frequent updates across 2,233 government websites.
- **Strict Liability Implications:** High standards of care required to avoid legal penalties.
- **Poor Tracking of Licenses:** Managing numerous licenses with different renewal timelines.
- **Event-Based Compliances:** Tracking specific events that trigger additional compliance requirements.
- **Manual Processes:** Reliance on paper-based systems and manual tracking.
- **Lack of Awareness:** Poor understanding of compliance obligations at the management level.

The report also prescribes recommendations for enabling Ease of Compliance. These action items include the creation of a Culture of Compliance and adopting Digital Solutions. Effective compliance management is critical for hospitals to ensure quality care and regulatory adherence. By implementing the recommended strategies, hospitals can streamline compliance processes, reduce the risk of non-compliance, and focus on delivering better healthcare services.

Overview of the Healthcare Sector

The Indian healthcare sector has witnessed remarkable growth and development in recent years. As per the Economic Survey 2022-23, India's public expenditure on healthcare increased to **2.1% of GDP in FY23 and 2.2% in FY22,** a notable rise from 1.6% in FY21. This surge underscores the government's commitment to enhancing healthcare infrastructure and services across the country.

The Indian healthcare market, valued at **US$ 372 billion,** is projected to reach **US$ 638 billion by 2025.** The $7+ billion medical tourism market is also projected to double by 2029. With around 630,000 international patients in 2023 alone, India has established itself as a global leader in advanced medical treatment. The sector is a major employer, with 7.5 million people employed as of 2024. The integration of Artificial Intelligence (AI) within the sector is expected to create nearly 3 million new jobs by 2028, further bolstering employment.

The e-health market is also poised for significant growth, with an estimated market size of US$ 10.6 billion by 2025. The doctor-to-population ratio in India stands at 1:854, assuming 80% availability of the 12.68 lac registered allopathic doctors and 5.65 lakh AYUSH doctors, as reported by Dr Bharati Pravin Pawar, Minister of Health & Family Welfare. This ratio highlights the availability of a large pool of well-trained medical professionals in the country.

Policy and government support have played a pivotal role in the sectoral growth. In the Interim Union Budget 2024-25, the government allocated Rs. **90,659 crore ($10.93 billion)** to the Ministry of Health and Family Welfare (MoHFW). Additionally, the government plans to introduce a credit incentive program worth Rs. **50,000 crore ($6.8 billion)** to enhance healthcare infrastructure.

Investment inflows have also been robust. Between April 2000 and December 2023, the drugs and pharmaceuticals sector received $22.37 billion in Foreign Direct Investment (FDI), while hospitals, diagnostic centres, and medical & surgical appliances sectors attracted **$9.81 billion and $3.26 billion,** respectively. During FY2022-23 (up to December 2022), FDI inflows in India stood at $36,746 million.

This report delves into the compliance landscape for hospitals in India, examining the regulatory frameworks, standards, and practices that govern healthcare delivery. It aims to provide an insight into the challenges and complexities faced by healthcare institutions such as hospitals in compliance management. It then provides actionable recommendations to help organisations transform their compliance culture and workflows.

Types of Healthcare Institutions

Hospitals

These are healthcare institutions with organised medical and other professional staff, and inpatient facilities deliver medical, nursing and related services 24 hours per day, 7 days per week. Hospitals offer a varying range of acute, convalescent and terminal care using diagnostic and curative services in response to acute and chronic conditions arising from diseases, injuries, and genetic anomalies.

Clinics and Medical Offices

Clinics and medical offices usually specialise in one or more areas of medicine and offer outpatient treatment that doesn't require an overnight stay for patients. Clinics and medical offices vary in size and staff and are either privately owned or part of a hospital or a larger healthcare network. These affiliations can affect the number of patients and the rules for referrals to other specialists. Some common clinics and medical offices are dental clinics, mental health clinics, community health clinics and physical therapy clinics.

Community Health Centres

Community health centres (CHCs) are established and maintained by the State Government under the MNP/BMS program in an area with a population of 120,000 people and in hilly/difficult-to-reach/tribal areas with a population of 80,000. As per minimum norms, a CHC is required to be staffed by four medical specialists, that is, surgeon, physician, gynaecologist/obstetrician and paediatrician, supported by 21 paramedical and other staff. It has 30 beds with an operating theatre, X-ray, labour room and laboratory facilities. It serves as a referral centre for PHCs within the block and also provides facilities for obstetric care and specialist consultations.

Hospice Homes

Hospice care facilities aim to improve the quality of life for people with advanced and end-stage illnesses, their families and their caregivers. Hospice centres differ from traditional health care settings because the goal of providers isn't to cure a patient's condition but to maximise their comfort through a variety of palliative care options, which help relieve pain. Additionally, hospice centres emphasise the role of family members by offering them support during the last stages of their loved one's life, including medical, psychological and spiritual support.

Dialysis Centers

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Mobile Clinics

There are fully-equipped mobile health centres that deliver health care to impoverished families in dozens of locations. Hundreds of patients daily benefit from on-site services and free medicines these mobile vans provide. This is the only time for the residents to see a doctor in remote areas. Immediate needs are met, referrals are made when necessary, and chronic diseases are identified and treated on an ongoing basis.

Nursing Homes

These are residential facilities that provide 24-hour care for older adults or people with disabilities. These facilities provide generalised or specialised care for patients with physical or mental health needs. Generally, the illnesses and injuries treated in nursing homes aren't serious enough to require hospitalisation but are too severe for home care. Some facilities specialise in different levels of treatment and care.

Blood Banks

Only licensed blood banks are permitted to collect, process, store, and transport blood and blood components. The safety and quality of blood and blood components is ensured by the State Drugs Control (Licensing Authority), the Drugs Controller General (India) and the Central Drugs Standard Control Organization (CDSCO) through licensing and periodic inspections.

Mental Healthcare Institutions

Mental health treatment facilities offer general psychiatric and psychological care or specialise in one area of psychiatry. These institutions provide inpatient and outpatient care, depending on the severity of patients' mental health needs.

Imaging and Radiology Centers

These types of facilities offer diagnostic imaging services, such as ultrasounds, computerised tomography (CT) scans, magnetic resonance imaging (MRIs), X-rays and other specialised imaging tests.

Addiction Treatment Centres

These centres typically handle issues with alcohol and drugs. Professionals can also treat other types of addictions, like gambling, video game and shopping addictions.

Birth Centers

Birth centres are healthcare facilities that specialise in childbirth. They aim to offer the mother and family a comfortable birth environment. Unlike hospitals, birthing centres don't usually have staff that readily provide obstetrics or neonatal care.

Rehabilitation Centres

Rehabilitation is care that can help you get back, keep, or improve your daily life abilities. These abilities may be physical, mental, and/or cognitive (thinking and learning). You may have lost them because of a disease or injury or as a side effect of a medical treatment. Rehabilitation can improve your daily life and functioning.

Many hospitals and clinics have this imaging equipment, but imaging and radiology centres offer a variety of tests and imaging services that doctor's offices may not. The availability of these centres can allow patients greater flexibility in scheduling their imaging appointments.

Diagnostic Centres

These stand-alone organised facilities provide simple to critical diagnostic procedures such as radiological investigation supervised by a radiologist and clinical laboratory services by laboratory specialists, usually performed through referrals from physicians and other health care facilities.

AYUSH

The Ayush system of medicine refers to India's traditional medicine system. It includes Ayurveda, Yoga & Naturopathy, Unani, Siddha, Sowa Rigpa and Homoeopathy. While Ayurveda has a history of over 5,000, the other systems covered under this system all have a long history of being used for medical treatment.

Regulatory Framework for Hospitals

In India, the regulatory framework for hospitals is complex and multifaceted, involving regulations at both the central and state levels. The regulatory landscape encompasses various authorities, standards, and compliance requirements, making it essential for healthcare entities to navigate multiple layers of regulations to ensure adherence and quality care delivery. For instance, the National Accreditation Board for Hospitals & Healthcare Providers (NABH) has developed comprehensive accreditation standards for hospitals covering various aspects of healthcare delivery, including patient care, clinical services, infrastructure, and management systems. These include:

- Ensuring patient rights, informed consent, confidentiality, and provision of information to patients.
- Implementing infection prevention and control measures to minimise healthcare-associated infections.
- Healthcare organisations are required to maintain comprehensive records of patient care, treatment protocols, adverse events, and quality improvement activities.
- Healthcare professionals must undergo regular training and competency assessments to maintain high standards of clinical practice and patient care.

In addition, there are compliances under the Drugs and Cosmetics Act, 1940, and Rules, 1945, Indian Council of Medical Research (ICMR) Guidelines, Telemedicine Practice Guidelines issued by the Ministry of Health and Family Welfare, and New Drugs and Clinical Trials Rules, 2019, to name a few. In addition, the corporate side of the industry is regulated by the MCA and other departmental-specific regulations.

In cases of professional negligence, patients are empowered to take legal action against the healthcare professional and, in some instances, the hospital. Liability arises from the criminal law system, consumer laws, and National Medical Commission regulations. Patients can simultaneously approach the criminal court, the consumer court, and the medical commission. Consequently, all of these authorities can penalise a medical professional/ hospital.

On the regulatory front, hospitals are subject to two kinds of compliances: one-time and ongoing. A single entity hospital operating in a single state is required to comply with 37 one-time registrations and approvals. These typically include incorporation of the entity, land allotment, approvals related to the project, construction, labour, environment, health and safety, tax-related registrations, and industry-specific approvals, among others.

Besides these one-time compliances, hospitals are subject to a variety of ongoing compliances at the central, state and local levels, given the decentralisation of power that characterises the Indian polity. For instance, labour laws fall in the concurrent list, wherein the Centre and States are entitled to legislate. Similarly, taxation and tax-related regulations are split between the Centre and States. Land is a state subject, but property transfer (including registration of deeds and documents) falls in the concurrent list. Electricity is again a subject on the concurrent list with laws at both the central and state levels. Additionally, hospitals must ensure compliance with local/municipal laws.

The regulatory requirements of hospitals can be classified into 7 broad categories:

- Labour
- Industry-Specific
- Finance & Taxation
- General
- Environment, Health & Safety
- Secretarial
- Commercial

While the requirements under most of these categories remain consistent and constant across industries and sectors, there are vast deviations regarding industry-specific requirements.

Table 1: List of Reporting Authorities for a Hospital*

Level of Governance	Reporting Authority
Central	Central Drugs Standard Control Organisation
	Chief Labour Commissioner
	Department of Atomic Energy
	Department of Consumer Affairs
	Department of Health and Family Welfare - Ministry of Health and Family Welfare
	Department of Pharmaceuticals
	Department of Revenue, Government of India
	Employees' State Insurance Corporation
	Food Safety and Standards Authority of India
	Ministry of Corporate Affairs
	Ministry of Electronics & Information Technology
	Ministry of Road Transport and Highways
	Ministry of Statistics and Programme Implementation
	Ministry of Women and Child Development
	National Medical Commission
State (Maharashtra)	Department of Goods an Service Tax, Govt. of Maharashtra
	Electrical Inspectorate, Industries, Energy and Labour Department, Govt. of Maharashtra
	Home Department of State of Maharashtra
	Labour Department, Govt. of Maharashtra
	Legal Metrology Organization, Govt. of Maharashtra
	Maharashtra Fire Services, Govt. of Maharashtra
	Maharashtra Labour Welfare Board, Labour Department, Govt. of Maharashtra

	Maharashtra Nursing Council
	Maharashtra Pollution Control Board
	Maharashtra Right to Public Service Commission
	Maharashtra State Pharmacy Council
	Public Health Department, Govt. Of Maharashtra
	Social Justice and Special Assistance Department, Govt. Of Maharashtra
	Welfare Commissioner, Labour Department, Govt. of Maharashtra
Municipal	Mumbai Municipal Corporation

**Single entity, 50-bed hospital with a diagnostic centre, radiology, pathology lab, and pharmacy with a corporate office operating in the Greater Mumbai*

APPROVALS

Every hospital must obtain close to 100 certificates, licenses, permissions, and approvals under at least 58 acts and rules at various stages of business from Central and State authorities. These stages can be classified as follows:

- **Setting Up**
- **Pre-Commissioning Stage**
- **Post-Commissioning Stage**
- **Post-Establishment**

Hospitals must adhere to numerous registration and approval requirements to ensure compliance with relevant regulations. These include obtaining a No Objection Certificate (NOC) for radiotherapy equipment and commissioning approval before energizing such equipment under the Atomic Energy (Radiation Protection) Rules, 2004. Additionally, hospitals must secure licenses for the commissioning and operation of medical diagnostic X-ray equipment. They also need authorisation from the Atomic Energy Regulatory Board (AERB) for procuring radiotherapy equipment like teletherapy machines, brachytherapy devices, simulators, CT simulators, and kV imaging systems.

Furthermore, approval of a Radiological Safety Officer is necessary for procuring any new radiotherapy equipment.

Hospitals must also register under the Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994, and pharmacists must be registered under the Indian Pharmacy Act, 1948. The Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985, requires a certificate of recognition for storing and using these substances. Under the Drugs and Cosmetics Act, 1940, and its associated rules, hospitals must obtain licenses for operating blood banks, retail and wholesale drug licenses, approval as a blood storage center, and an NOC from the State Blood Transfusion Council (SBTC). For organ transplantation, hospitals must register under the Transplantation of Human Organs Act, 1994, for both the transplantation of human organs and the registration of tissue banks. Finally, hospitals must secure licenses for establishing or maintaining psychiatric hospitals or nursing homes in accordance with the Mental Healthcare Act, 2017, and the Mental Healthcare (State Mental Health Authority) Rules, 2018.

Figure 1: Distribution of Approvals, Permissions, etc. on the basis of Acts

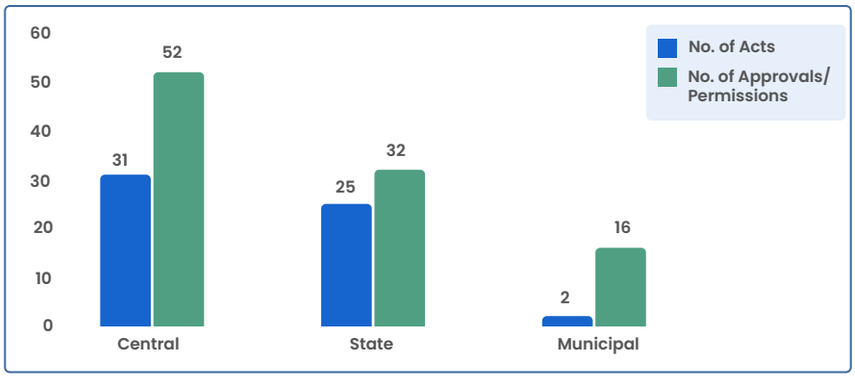
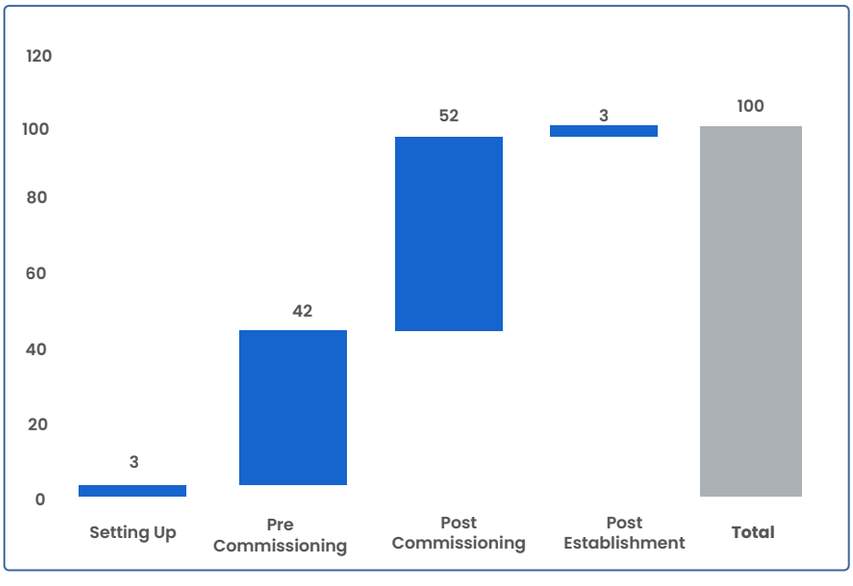


Figure 2: Approvals across the stage of business



Furthermore, these approvals can also be classified based on the 7 categories of compliance.

Figure 3: Approvals to Establish, Start, and Continue Operations across Compliance Categories

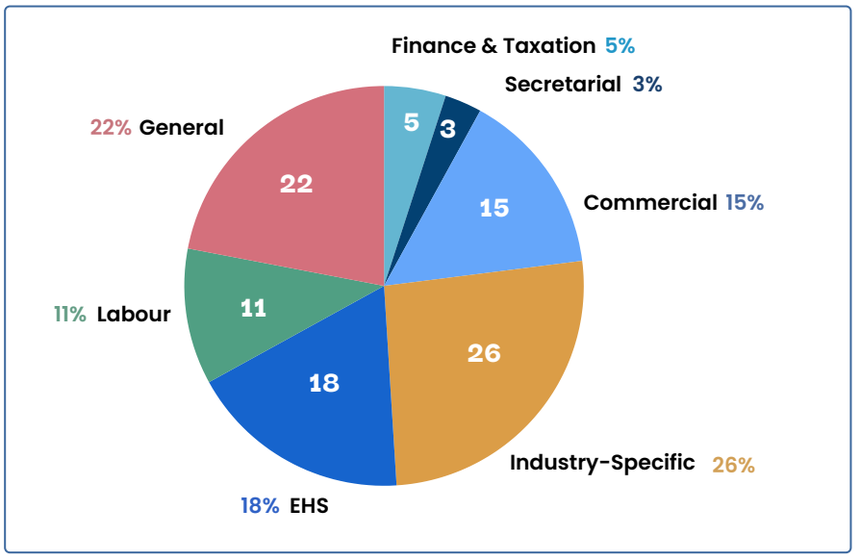


Table 2: An illustrative list of licenses, permissions etc., has been presented below

Name of Legislation	Approvals / Registrations / Permissions
Air (Prevention & Control of Pollution) Act, 1981, Water (Prevention & Control of Pollution) Act, 1974, Environment Protection Act, 1986	Consent to Establish & Consent to Operate
Ancient Monuments and Archaeological Sites and Remains (Amendment and Validation) Act, 2010	NOC from the Department of Cultural Affairs, Directorate of Archaeology, if the project site is near the monuments
The Apprentices Act, 1961 & Apprenticeship Rules, 1992	Registration of Establishment
Arms Act, 1959 & Arms Rules, 2016	Licence for acquisition and possession of firearms and ammunition
Atomic Energy (Radiation Protection) Rules, 2004	Approval of the Radiological Safety Officer for obtaining procurement permission for any Radiotherapy equipment in the new Radiotherapy facility Approval of survey report Authorisation from AERB for procurement of equipment (e.g. Teletherapy equipment, Brachytherapy equipment, Simulator, CT-Simulator and kV imaging system) and radioactive sources to be used in Radiotherapy equipment Commissioning approval before energising equipment for radiation Licence/Registration for Commissioning / Operation of Medical Diagnostic X-Ray Equipment Registration for operation of Medical Diagnostic X-ray Equipment Type approval certificate or NOC for Radiotherapy equipment
Bombay Prohibition Act, 1949 & Bombay Rectified Spirit Rules, 1951	Permission to use spirit
Building and Other Construction Workers (Regulation of Employment and Conditions of Service) Act, 1996 and Maharashtra Building and Other Construction Workers (Regulation of Employment and Conditions of Service) Rules, 2007	Registration of Establishment
Coastal Regulation Zone Notification, 2011	Coastal Regulation Zone Clearance
Companies Act, 2013 & Companies (Incorporation) Rules, 2014 Companies Act, 2013	Private Limited Company - Digital Signature Certificate (DSC) & Director Identification Number (DIN) Approval for Name & Certificate of Incorporation
Contract Labour (Regulation & Abolition) Act, 1970 & Maharashtra Contract Labour (Regulation & Abolition) Rules, 1971	Registration of Principal Employer

Dentists Act, 1948	Registration of dentists in the State Register or the Indian Dentist Register (To be done by dentists but checked by Hospital)
Drugs and Cosmetics Act, 1940 & Drugs and Cosmetics Rules, 1945	Personnel Approval of Blood Storage Centre (To be done by Technician and medical oficer) Approval as Blood Storage Centre in Annexure C License for operating blood bank Retail Drug License Wholesale Drug License NOC by State Blood Transfusion Council (SBTC)
EIA Notification, 2006	Environment Clearance
Electricity Act, 2003 & Central Electricity Authority (Measures Relating To Safety and Electric Supply) Regulations, 2023	Consent for setting up captive power plant Final Electrical Installation Certificate Permission for charging of MSEDCL line for more than 650 Volts
Employees' State Insurance Act, 1948	Registration of Establishment
Maharashtra Electricity Duty Act, 2016 and Maharashtra Electricity Duty Rules, 1962	Layout Approvals for DG sets Permission for charging Diesel Generator Sets for more than 250 KV Registration of Diesel Generator Sets
Employee Provident Funds and Miscellaneous Provisions Act, 1952 and Employees Provident Fund Scheme, 1952 (EPFS), Employees Pension Scheme, 1995 (EPS), Employees Deposit-linked Insurance Scheme, 1976 (EPLIS)	Registration of Establishment
Environment Protection Act, 1986 & Bio-Medical Waste Management Rules, 2016	Authorisation for handling bio-medical waste
Explosives Act, 1884	NOC for controlled Blasting for Excavation
Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011	FSSAI license for operating a kitchen(License for food business)
Gas Cylinder Rules, 2016	License for storage of LPG
Guidelines to regulate and control Ground Water Extraction in India (With effect from 01.06.2019)	Permission/ Clearance for abstraction of groundwater/ drilling for Industrial purposes

Income Tax Act, 1961	Obtaining PAN Obtaining TAN Income tax exemption Certificate
Indian Boilers Act, 1923 Registration of Boiler	Indian Boilers Act, 1923 Registration of Boiler
Indian Forest Act, 1927 & Maharashtra Forest Rules, 2014	Tree Transit Pass
Indian Medical Council Act, 1956	Registration of doctors in State Medical Register or the Indian Medical Register (To be done by doctors but checked by the Hospital)
Indian Nursing Council Act, 1947 Maharashtra Nurses Act, 1966 Maharashtra Nursing Council Rules, 1971 Maharashtra Nursing Council By-Laws, 1973	Registration of nurses in the State Medical Register or the Indian Medical Register (To be done by nurses but checked by the Hospital)
Indian Pharmacy Act, 1948	Registration of Pharmacists
Inter-State Migrant Workmen (Regulation of Employment and Conditions of Service) Act, 1979 and Inter-State Migrant Workmen (Regulation of Employment and Conditions of Service) (Maharashtra) Rules, 1985	Registration of the establishment
Legal Metrology Act, 2009 & Maharashtra Legal Metrology (Enforcement) Rules, 2010	Verification of weight or measure before putting into use
Maharashtra (Mumbai) Nursing Homes Registration Act, 1949 & Maharashtra Nursing Homes Registration Rules, 1973	Registration of Nursing Homes
Maharashtra Electricity Regulatory Commission (Standards of Performance of Distribution Licensees, Period for Giving Supply and Determination of Compensation) Regulations, 2014	Power Connection for Construction
Maharashtra Fire Prevention and Life Safety Measures Act, 2006	Final Fire NOC Fire Safety Certificate Provisional Fire NOC
Maharashtra Goods and Services Tax Act, 2017	Obtaining GSTN
Maharashtra Labour Welfare Fund Act, 1953 & Bombay Labour Welfare Fund Rules, 1953	Registration of Establishment
Maharashtra Land Revenue Code, 1966 & Maharashtra Land Revenue (Restriction on use of Land) Rules, 1968	NOC for Excavation/Royalty Payment

Maharashtra Lifts, Escalators & Moving Walks Act, 2017	Approval for Lift / Elevator for Plant (Passenger Lifts) License to Operate Lifts
Maharashtra Mathadi, Hamal and other manual Workers (Regulation of Employment and Welfare) Act, 1969	Registration of Employer
Maharashtra Private Security Guards (Regulation of Employment and Welfare) Act, 1981 & Maharastra Private Security Guards (Regulation of Employment and Welfare) Scheme, 2002	Registration of Principal Employer
Maharashtra Regional Town Planning Act, 1966	Health License
Maharashtra Shops and Establishments (Regulation of Employment and Conditions of Service) Act, 2017 & Maharashtra Shops and Establishments (Regulation of Employment and Conditions of Service) Rules, 2018	Registration of Hospital / Clinical Establishment
Maharashtra State Tax on Professions, Trades, Callings and Employments Act, 1975	PTEC / PTRC
Medical Termination Of Pregnancy Act, 1971 & Medical Termination of Pregnancy Rules, 2003	Certificate of Approval in Form B(Registration under Medical Termination Of Pregnancy Act, 1971)
Mental Healthcare Act, 2017 & Mental Healthcare (State Mental Health Authority) Rules, 2018	License for establishment or maintenance of psychiatric hospitals or psychiatric nursing homes
Micro, Small and Medium Enterprises Development Act, 2006	Entrepreneurship Memorandum Part-1 Under MSME Act, 2006 Entrepreneurship Memorandum Part-2 Under MSME Act, 2006 Udyam Registration Certificate (e-Certificate) Udyam Registration Number
Motor Vehicles Act, 1988 & Maharashtra Motor Vehicles Rules, 1989	Vehicle Registration Certificate (For all hospital vehicles)
Mumbai Municipal Corporation Act, 1888	Issue of No Due Certificate Building Completion Certificate Building Layout Approval Commencement Certificate / Construction Permit Intimation of disapproval (Building Permit) NOC for Storm Water and Drain NOC from Sewarage Department

	NOC from the Traffic and Co-ordination Department Non-Agriculture Permission Occupancy Certificate Ownership Certificate / Extract Permanent Water Connection Plinth Completion Certificate Water Connection for Construction
Maharashtra Felling of Trees (Regulation) Act, 1964	Permission for Felling / Trimming / Re-plantation of trees
Narcotic Drugs and Psychotropic Substances Act, 1985	Certificate of Recognition for storing and usage of Narcotic Drugs and Psychotropic Substances (NDPS)
National Accreditation Board for Testing and Calibration Laboratories (NABL)	Accreditation from the National Accreditation Board for Testing and Calibration Laboratories
No Objection Certificate (NOC) for height clearances - Air Traffic Management Circular No. 6 of 2017Guidelines for Filing Online Application for NOC (Height Clearance) Through NOCAS, NOC Revalidation and Appeal to the Appellate Committee (MoCA)	NOC from Airport Authority
Payment of Gratuity Act, 1972 and Payment of Gratuity (Maharashtra) Rules, 1972	Registration of the establishment(Notice of Opening)
Petroleum Act, 1934	License for storage of Petroleum products (Class B)
Poisons Act, 1919 & Maharashtra Poisons Rules, 1972	License for storage and usage of Acid / Poisons
Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994	Certificate of registration
Registration Act, 1908	Registration of Land with the Department of Registration & Stamps
The Control of National Highways (Land & Traffic) Act, 2002 Guidelines / Norms for Grant of permissions for construction of access to Fuel Stations, Wayside amenities, connecting roads, other properties, rest area complexes & such other facilities dated 26th June 2020	Permission for Highway Crossing, access road through highway, right of way etc.
Transplantation of Human Organs Act, 1994	Certification of Registration of hospital for transplantation of human organs Certification of Registration of Tissue Bank

Table 3: Illustrative list of authorities responsible for multiple approvals

Issuing Authority	Number of Approvals/ Registrations/ Permissions
Municipal Corporation of Greater Mumbai	12
Atomic Energy Regulatory Board (AERB)	7
Labour Commissioner	5
Maharashtra Pollution Control Board (MPCB)	4
Department for Micro, Small and Medium Enterprises (MSME)	4
Registrar of the Companies (ROC)	3
Maharashtra State Electricity Distribution Co. Ltd.	3
Director Maharashtra Fire & Emergency Services Chief Fire Officer (CFO)	3
Public Works Department (Electrical)	3

However, the complexities do not end there. These registrations, licenses, permissions, etc., all have different timelines for their approval. This affects the hospital's business planning and operations as some approvals take much longer than others.

Table 4: Timeline for obtaining Approvals, Registrations & Permissions

Timeline for Approval, Registration, Permission	Number of Approvals, Registrations, Permissions
1 to 15 Days	18
15 to 30 Days	22
30 to 90 Days	13
90 to 196 Days	7
No timeline	2
Issued on the Same Day	2
Others	34

Additionally, each license/ permission/ registration/ approval requires hospitals to pay a different fee. This can be either a fixed fee or calculated based on several factors, such as the project's total area, total investment, and number of employees. Furthermore, there are additional registrations, certifications, approvals etc., that become applicable once the hospital starts operations, increasing the complexity of compliance. The very nature of compliances also differs based on their level (Governance level), category, and type.

**Single entity, 50-bed hospital with a diagnostic centre, radiology, pathology lab, and pharmacy with a corporate office operating in the Greater Mumbai*

LEVELS OF COMPLIANCE

The overlapping of legislative powers among the union and the state governments adds another layer of complexity to the regulatory framework. For instance, 'labour' and 'electricity' fall under the concurrent list of the seventh schedule of the Constitution of India, empowering both the union and state governments to legislate on it. As a result, a company must comply with not only Union laws but also the laws of the state in which it operates. A particularly complex situation is that of 'Land' as it is a state subject, but 'transfer of property excluding agricultural land' falls under the concurrent list.

Yet another example is 'taxation'. The power to impose and collect taxes on different matters has been spread across the union, state and concurrent lists. Thus, some taxes (such as corporate tax) are payable to the union government, while others (such as stamp duty) are payable to the state government. Some taxation powers (such as property tax) have also been devolved to municipal bodies.

This division of law-making authority across various levels of government has created three levels of compliance - union, state and municipal.

On average, a single entity, 50-bed hospital with a diagnostic centre, radiology, pathology lab, and pharmacy with a corporate office operating in the Greater Mumbai area in the state of Maharashtra faces 623 unique obligations, of which 421 (67.5%) are at the union level, 192 (31%) are at the state level, and 10 (1.5%) are at the municipal level. In terms of frequency of these compliances, there are 27 monthly, 12 quarterly, 11 half-yearly and 47 annual compliances. Ongoing, checklisted, event-based and other compliances account for 523 obligations.

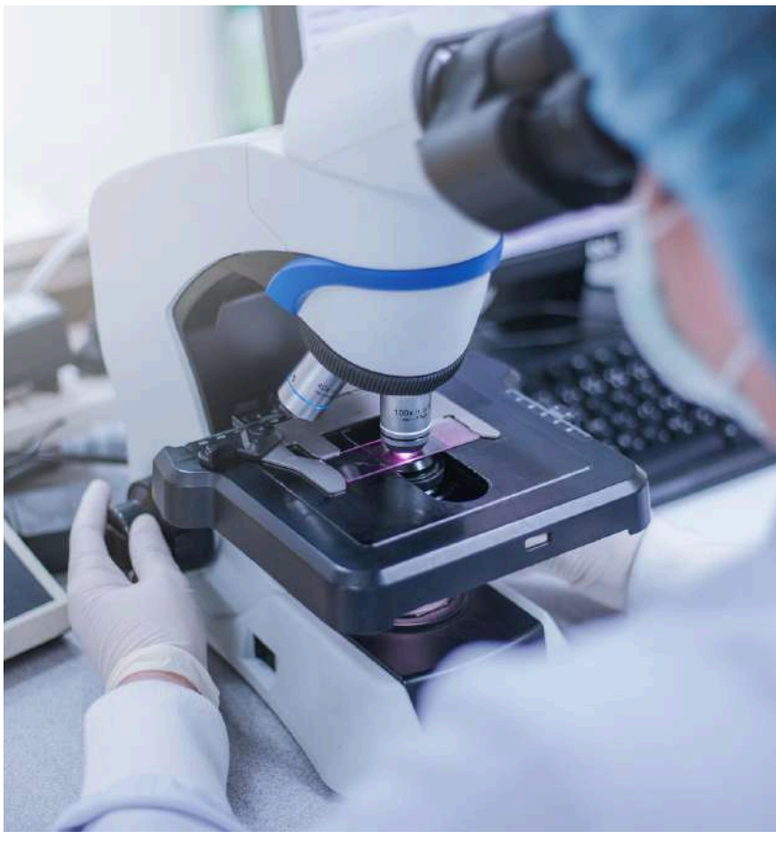
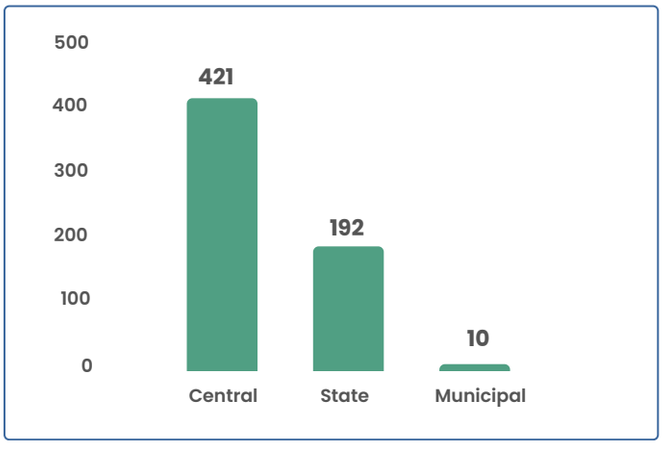


Figure 4: Compliances at Central, State, and Municipal Levels for a Hospital*



**Single entity, 50-bed hospital with a diagnostic centre, radiology, pathology lab, and pharmacy with a corporate office operating in the Greater Mumbai*

3.3 CATEGORIES OF COMPLIANCES

The compliance requirements for a hospital can be broadly classified across seven categories. Each of these categories contains several laws, rules and regulations with varying degrees of applicability depending on the company's size, nature and operations. A typical single-entity 50-bed hospital with a diagnostic centre, radiology, pathology lab, and pharmacy with a corporate office in a single state needs to deal with 623 unique compliances. However, this figure inflates to 967 once we factor in the annual frequency of these obligations. This figure can go even higher given the nature of ongoing and event-based compliances that do not have a fixed frequency.

Table 5: Category-wise frequency of compliances for a hospital* in a single state

Category	Frequency								
	Seven Yearly	Five Yearly	Two Yearly	Annual	Half Yearly	Quarterly	Monthly	Others (Event-Based, One-Time)	Total
Labour	1	-	-	14	6	4	12	154	191
Finance and Taxation	-	-	-	10	-	5	11	17	43
Environment, Health and Safety (EHS)	-	-	-	4	2	-	2	115	123
General	-	-	-	2	-	-	-	16	18
Commercial	1	-	-	3	2	1	2	17	26
Secretarial	-	1	-	12	1	1	-	36	51
Industry Specific	-	-	-	2	-	1	-	168	171
Total	2	1	-	47	11	12	27	523	623
Total Annual Obligations (annual freq. X no. of compliances)	2	1	-	47	22	48	324	523	967

Source: TeamLease RegTech

**Single entity, 50-bed hospital with a diagnostic centre, radiology, pathology lab, and pharmacy with a corporate office operating in the Greater Mumbai*

Labour

This category includes 29 union laws that have now been consolidated into four labour codes. Since labour is a subject in the concurrent list, it is legislated by the union government, and each of these laws is accompanied by a host of state legislations. There are also various delegated legislations, such as rules and regulations, both at the union and state levels. As such, hospitals must create a list of applicable acts, rules and regulations to understand their obligations better.

Presented below is an illustrative list of applicable regulations under labour compliance:

- Contract Labour (Regulation & Abolition) Act, 1970 & Maharashtra Contract Labour (Regulation & Abolition) Rules, 1971
- Employees Compensation Act, 1923 & Maharashtra Employees's Compensation Rules, 1934
- Employees State Insurance Act, 1948 & Employees State Insurance (General) Regulations, 1950 & Employees State Insurance (Central) Rules, 1950
- Employment Exchange (Compulsory Notification of Vacancies) Act, 1959 & Employment Exchange (Compulsory Notification of Vacancies) Rules, 1960
- Equal Remuneration Act, 1976 and Equal Remuneration Rules, 1976
- Maharashtra Labour Welfare Fund Act, 1953 & Bombay Labour Welfare Fund Rules, 1953
- Maharashtra Private Security Guards (Regulation of Employment and Welfare) Act, 1981 & Maharashtra Private Security Guards (Regulation of Employment and Welfare) Scheme, 2002
- Maharashtra Shops and Establishments (Regulation of Employment and Conditions of Service) Act, 2017 and Maharashtra Shops and Establishments (Regulation of Employment and Conditions of Service) Rules, 2018
- Maharashtra Workmen's Minimum House-Rent Allowance Act, 1983 & Maharashtra Workmen's Minimum House-Rent Allowance Rules, 1990
- Maternity Benefit Act, 1961 and Maharashtra Maternity Benefit Rules, 1965
- Minimum Wages Act, 1948 & Maharashtra Minimum Wages Rules, 1963
- Payment of Bonus Act,1965 & Payment of Bonus Rules, 1975
- Payment of Gratuity Act, 1972 and Payment of Gratuity (Maharashtra) Rules, 1972
- Rights of Persons with Disabilities Act, 2016 and Rights of Persons with Disabilities Rules, 2017
- Sexual Harassment of Women at Workplace (Prevention, Prohibition & Redressal) Act, 2013 & Sexual Harassment of Women at Workplace (Prevention, Prohibition & Redressal) Rules 2013

Hospitals must adhere to several labour regulations to ensure the welfare and rights of their employees. For instance, they are required to maintain a Register of Contractors in Form VIII under the Contract Labour (Regulation & Abolition) Act, 1970, and the Maharashtra Contract Labour (Regulation & Abolition) Rules, 1971. Additionally, they must keep a Register of Employees in Form 6 as mandated by the Employees State Insurance Act, 1948, and its associated regulations and rules. Hospitals are also responsible for providing and maintaining first aid facilities for their workers and providing identity cards to its workers in accordance with the Maharashtra Shops and Establishments (Regulation of Employment and Conditions of Service) Act, 2017, and its rules. Furthermore, they must also maintain a Muster Roll cum Wage Register in Form II as stipulated by the Minimum Wages Act, 1948, and the Maharashtra Minimum Wages Rules, 1963. In addition, they are required to frame and publish an equal opportunity policy for disabled persons under the Rights of Persons with Disabilities Act, 2016, and the Rights of Persons with Disabilities Rules, 2017. These are some of the several labour compliance obligations that compliance teams must manage.

Secretarial

Secretarial compliances comprise legislation related to corporate governance and risk management. While the union government enacts the laws, the rules and regulations are issued by the Ministry of Corporate Affairs (MCA), Securities and Exchange Board of India (SEBI), etc. There are several rules and regulations under the overarching Companies Act, 2013.

Presented below is an illustrative list of applicable regulations under secretarial compliance:

- Companies Act, 2013 and Companies (Acceptance of Deposits) Rules, 2014
- Companies Act, 2013 and Companies (Accounts) Rules, 2014
- Companies Act, 2013 and Companies (Appointment and Qualification of Directors) Rules, 2014
- Companies Act, 2013 and Companies (Audit and Auditors) Rules, 2014
- Companies Act, 2013 and Companies (Incorporation) Rules, 2014
- Companies Act, 2013 and Companies (Corporate Social Responsibility) Rules, 2014
- Companies Act, 2013 and Companies (Management and Administration) Rules, 2014
- Companies Act, 2013 and Companies (Meetings of Board and its Powers) Rules, 2014
- Companies Act, 2013 and Companies (Registration of Charges) Rules, 2014
- Companies Act, 2013 and Companies (Significant Beneficial Owners) Rules, 2018
- Companies Act, 2013 & Companies (Share Capital and Debentures) Rules, 2014
- Companies Act, 2013 and Companies (Cost Records and Audit) Rules, 2014
- SS-1 Secretarial Standard on Meetings of the Board of Directors
- SS-2 Secretarial Standard On General Meetings

Under the secretarial category, hospitals are required to maintain a register of significant beneficial owners in Form No. BEN-3 as per the Companies (Significant Beneficial Owners) Rules, 2018. Additionally, hospitals must keep detailed cost records in Form CRA-1 under the Companies (Cost Records and Audit) Rules, 2014. The Companies Act, 2013, and the Companies (Accounts) Rules, 2014 calls for the preparation and maintenance of book of accounts and maintenance of financial statements as per the outlined accounting standards.

Finance and Taxation

This category includes laws on direct taxes (Income Tax, Property Tax and Corporate Tax) and on indirect taxes (GST, Excise Duty, and Customs Duty).

Presented below is an illustrative list of applicable regulations under finance and taxation compliance:

- Income Tax Act, 1961 and Income Tax Rules, 1962
- Central GST Act, 2017 and Central GST Rules, 2017
- Maharashtra GST Act, 2017 and Maharashtra GST Rules, 2017
- Maharashtra State Tax on Professions, Trades, Callings and Employments Act,1975 and Maharashtra State tax on Professions, Trades, Callings and Employments Rules, 1975
- State-specific laws for taxes on professions, trades, callings and employment

Under the Maharashtra State Tax on Professions, Trades, Callings, and Employments Act, 1975, and its subordinate rules, hospitals are required to maintain a register of salaries, wages, and deductions and furnish a monthly return in Form IIIB (PTRC), detailing the same. The Income Tax Act, 1961, and Income Tax Rules, 1962, mandate that hospitals to submit their audit report in Form 3CD and submit quarterly TDS returns for foreign payments.

Under the Central Goods and Services Tax Act, 2017, and the Maharashtra Goods and Services Tax Act, 2017, along with their respective rules, hospitals are required to furnish an annual return in Form GSTR-9. They must also maintain and preserve backups for electronic records of documents to ensure compliance with GST regulations. These requirements are crucial for maintaining transparency, ensuring accurate financial reporting, and adhering to tax obligations, thus upholding legal and fiscal accountability. These are some of the several finance & taxation related compliance obligations that compliance teams must manage.

Environment, Health and Safety (EHS)

This category covers all environmental issues, such as pollution, waste management, and hazardous substance discharge. It comprises regulations related to Air, Water and Noise Pollution and Waste Management (Bio-Medical, Solid Waste, E-Waste, Plastic Waste, and Hazardous Waste), among others.

Presented below is an illustrative list of applicable regulations under EHS compliance:

- Atomic Energy Act, 1962 and Atomic Energy (Radiation Protection) Rules, 2004
- Bureau of Indian Standards Act, 2016 read with Indian Standard - Selection, Installation and Maintenance of First-Aid Fire Extinguishers - Code of Practice
- Constructional and Functional Requirements for Road Ambulances (National Ambulance Code)
- Environment (Protection) Act, 1986 & Environment (Protection) Rules, 1986
- Environment (Protection) Act, 1986 and Battery Waste Management Rules, 2022
- Environment (Protection) Act, 1986 and Bio-Medical Waste Management Rules, 2016
- Environment (Protection) Act, 1986 and E-Waste (Management) Rules, 2022
- Environment (Protection) Act, 1986 and Noise Pollution (Regulation And Control) Rules, 2000
- Environment (Protection) Act, 1986 and Plastic Waste Management Rules 2016
- Environment (Protection) Act, 1986 and Solid Waste Management Rules, 2016
- Maharashtra Fire Prevention and Life Safety Measures Act, 2006 and Maharashtra Fire Prevention and Life safety Measures Rules, 2009
- Patient's Rights and Responsibilities in all Clinical Establishment vide D.O. No. Z.28015/09/2018-MH-II/MS dated June 02, 2019

EHS compliances also constitute an integral part of the regulatory framework for hospitals. For instance, they must adhere to the Indian Standard for the Selection, Installation, and Maintenance of First-Aid Fire Extinguishers under the Bureau of Indian Standards Act, 2016. This includes regular inspection and maintenance of fire extinguishers, keeping records, placing extinguishers in conspicuous places, maintaining at least 10% of spare refills in stock, and conducting annual inspections.

Compliance with the Solid Waste Management Rules, 2016, mandates the segregation of dry and non-biodegradable waste. Under the Atomic Energy Act, 1962, and Atomic Energy (Radiation Protection) Rules, 2004, hospitals must conduct health surveillance of workers every three years, display radiation symbols or warning signs, and establish written procedures for controlling and monitoring exposure to ensure adequate protection. This includes maintaining records of workers, ensuring preventive maintenance of radiation protection equipment, periodic verification of radioactive material, and conducting quality assurance tests. Records of radiation doses received by therapy patients and other relevant parameters must be maintained, and the radiological safety officer must submit periodic safety reports to the competent authority.

The Bio-Medical Waste Management Rules, 2016, require hospitals to submit an annual report in Form-IV, establish a bar-code system for bio-medical waste bags or containers, maintain a daily updated bio-medical waste management register, and display monthly records of waste generated on the hospital's website. Records for the operation of incineration, hydro, or autoclaving must be maintained for five years, along with records related to the generation, collection, reception, storage, transportation, treatment, and disposal of bio-medical waste. Annual reports and minutes of committee meetings must be submitted to the prescribed authority, such as the State Pollution Control Committee. These are some of the several EHS compliance obligations that compliance teams must manage.

Commercial

This category includes all laws overseeing the production and trade of goods and services.

Presented below is an illustrative list of applicable regulations under Commercial compliance:

- Collection of Statistics Act, 2008 and Collection of Statistics (Central) Rules, 1959
- Motor Vehicles Act, 1988 and Central Motor Vehicle Rules, 1989
- Food Safety & Standards Act, 2006 & Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011
- Legal Metrology Act, 2009 and Maharashtra Legal Metrology (Enforcement) Rules, 2011
- Maharashtra Electricity Duty Act, 2016 and Maharashtra Electricity Duty Rules, 1962

Hospitals need to adhere to certain commercial obligations, stemming from food business operations on its premises and the usage of electricity, motor vehicles, and weights and scales. Under the Food Safety & Standards Act, 2006, and the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011, they must provide an adequate supply of potable water to meet operational and cleanup needs. Additionally, the maintenance of floors and ceilings is required to maintain hygiene.

In case the hospital is also a captive generator of electricity, the Maharashtra Electricity Duty Act, 2016, and Maharashtra Electricity Duty Rules, 1962, mandate the submission of a quarterly return in Form B. Furthermore, under the Legal Metrology Act, 2009, and the Maharashtra Legal Metrology (Enforcement) Rules, 2011, weights, capacity measures, length measures, tape measures, beam scales, and counter machines must be re-verified every two years.

General

All legislations that are not under any of the other six categories are categorised as general laws.

Presented below is an illustrative list of regulations under General compliance:

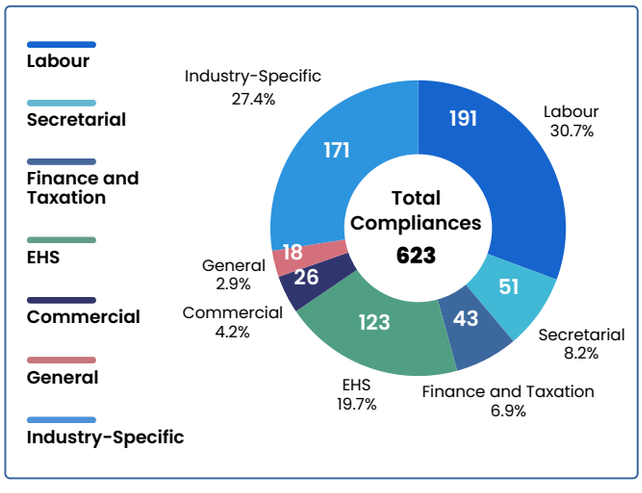
- Cigarette and Other Tobacco Products (Prohibition of Advertisement and the Regulation of Trade and Commerce,Production, Supply and Distribution) Act, 2003 & Prohibition of Smoking in Public Places Rules, 2008
- Information Technology Act, 2000 and Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011
- Disaster Management Act, 2005 and underlying directions
- Information Technology Act, 2000 and Information Technology (The Indian Computer Emergency Response Team and Manner of Performing Functions and Duties) Rules, 2013
- Mumbai Municipal Corporation Act, 1888

Hospitals must comply with regulations under the Information Technology Act 2000 and the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011. They are required to maintain reasonable security practices for data protection. This includes conducting annual audits to ensure these security practices and procedures are adequately implemented and maintained. Additionally, hospitals must comply with the Cigarette and Other Tobacco Products (Prohibition of Advertisement and the Regulation of Trade and Commerce, Production, Supply, and Distribution) Act, 2003, and the Prohibition of Smoking in Public Places Rules, 2008, by displaying "NO SMOKING AREA" signs at the entrances.

Industry Specific

Apart from the above mentioned several different types of compliances, hospitals must also manage a variety of industry-specific compliances. As indicated earlier, hospitals are often involved in bio-hazardous processes and therefore, the risk stemming from non-compliance is concomitantly high. Many of the compliances that compliance officers are required to manage to find their roots in international conventions. This subsection will elaborate on the applicable industry-specific compliances:

Figure 5: Category-Wise Compliances for a Hospital* in a single state



However, the number of compliance obligations can vary depending on the state.

Presented below is an illustrative list of regulations under industry-specific compliance:

- Atomic Energy Act, 1962 and Radiation Safety in Manufacture, Supply and Use of Medical Diagnostic X-Ray Equipment
- Atomic Energy Act, 1962 and Radiation Surveillance Procedures for Medical Application of Radiation, 1989
- Clinical Establishments (Registration and Regulation) Act, 2010 and Clinical Establishment (Central Government) Rules, 2012
- Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945
- Drugs and Cosmetics Act, 1940 and Schedule N - List of minimum equipment for the efficient runninig of a pharmacy
- Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 and Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955
- Essential Commodities Act, 1955 and Drugs (Price Control) Order, 2013
- Guidelines for Protection of Good Samaritans - Notification No. 25035/101/2014-RS. dated May 12, 2015
- Indian Medical Council Act, 1956 and Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002
- Indian Medical Council Act, 1956 and Integrated Disease Surveillance Project, 2004
- Indian Medical Council Act, 1956 and Maternal Death Review Guidelines
- Indian Medical Council Act, 1956 and Medical Council of India Regulations, 2000
- Indian Medical Council Act, 1956 and TB Notification Guidance, 2012
- Maharashtra Nurses Act, 1966 and Maharashtra Nursing Council Rules, 1971

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- Maharashtra Nursing Homes Registration Act, 1949 and Maharashtra Nursing Homes Registration Rules, 1973
- Medical Termination of Pregnancy Act, 1971 and Medical Termination of Pregnancy Rules, 2003
- Narcotic Drugs and Psychotropic Substances Act, 1985 and Maharashtra Narcotic Drugs and Psychotropic Substances Rules, 1985.
- Narcotic Drugs and Psychotropic Substances Act, 1985 and Narcotic Drugs and Psychotropic Substances (Regulation of Controlled Substances) Order, 2013
- Pharmacy Act, 1948 and Maharashtra State Pharmacy Council Rules, 1969
- Pharmacy Act, 1948 and Pharmacy Practice Regulations, 2015
- Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 and Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996
- Registration of Births and Deaths Act, 1969 and Maharashtra Registration of Births and Deaths Rules, 1976

Hospitals must adhere to various regulatory requirements to ensure compliance with the Narcotic Drugs and Psychotropic Substances Act, 1985, and the Maharashtra Narcotic Drugs and Psychotropic Substances Rules, 1985. This includes making annual disclosures to the licensing authority regarding the purchase and consumption of manufactured drugs and maintaining detailed accounts of drugs received, used, and held in stock.

Under the Pharmacy Act, 1948, and the Pharmacy Practice Regulations, 2015, hospitals are required to maintain patient records for five years, along with proper documentation of compounding, labeling, dispensing of drugs, and prescription records. Additionally, hospitals must document and maintain records of drugs administered to patients and inform authorities about any cases of communicable diseases. The Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994, mandates that hospitals preserve the names of individuals who have received genetic counseling for two years.

The Indian Medical Council Act, 1956, and the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, require physicians to maintain medical records for indoor patients for three years, keep a register of medical certificates issued, notify public health authorities of communicable diseases, and maintain comprehensive patient records, including case histories, investigation reports, images, and prescription records for in-person consultations.

FIRE SAFETY COMPLIANCES

In recent years, fire-related incidents in hospitals have been on a rise. According to the National Crime Records Bureau (NCRB), Maharashtra and Gujarat together accounted for 30 percent of fire-related fatalities last year. Electrical faults and human negligence were cited as primary causes. Delhi has also reported numerous hospital fires in the past few years. In most instances of fires, local authorities have been found negligent in conducting routine fire safety audits. Fire services in India fall under state jurisdiction and are considered a municipal function. However, statutory bodies issue guidelines and recommendations that prescribe the regulatory framework for fire safety. Fire safety regulations in India are published by the Bureau of Indian Standards (BIS) under the National Building Code (NBC). The National Disaster Management Authority (NDMA) also mandates specific fire safety criteria for public structures such as hospitals, including provisions for open safety spaces, evacuation procedures, dedicated staircases, and evacuation drills.

The most common causes of fires in hospitals include the presence of combustible materials like cotton beddings, sanitizers, oxygen pipeline connections in patient rooms and operation theatres, and chemicals in laboratories. Faulty electrical wiring or frayed wires often cause electrical short circuits in hospitals. In modern constructions, these wires are concealed, making it difficult to track the source of the fire.

Fire Prevention Standards

National Building Code

The NBC outlines several fire prevention standards. Some of them are enlisted below:

- Buildings with a total covered area of 500 m² and above must protect load-bearing steel beams and columns against failure or collapse in case of fire.
- An emergency power distribution system is necessary for fire and life safety systems and equipment, including fire pumps, pressurisation and smoke venting systems, fireman's lifts, exit signage lighting, emergency lighting, fire alarm systems, public address (PA) systems, magnetic door hold/open devices, and lighting in the fire command centre and security room.
- Air conditioning and ventilating systems must be installed and maintained to minimize the danger of spreading fire, smoke, or fumes from one floor to another or from outside to any occupied building.
- Fire doors with a 120-minute fire-resistance rating are required for non-naturally ventilated areas, and all exits and exit passageways must have a clear ceiling height of at least 2.4 meters.
- Additionally, gas pipes should be run on external walls in separate shafts away from staircases, and pump houses should be separated by firewalls, with doors protected by fire doors with a 120-minute rating. The pressure in the sprinkler system should not exceed 12 bar; if higher pressure is required, high-pressure sprinklers must be installed.

National Accreditation Board for Hospitals & Healthcare Providers (NABH) Recommendations

The NABH has also published recommendations for fire safety. These include:

- Conducting regular fire risk assessments and audits to identify vulnerabilities and ensure compliance with fire safety regulations.
- Implementing robust fire prevention measures, including properly storing flammable materials, maintaining electrical systems, and installing fire detection and suppression systems.
- Providing regular training to staff members on fire evacuation procedures, including the safe evacuation of patients with special needs.
- Periodically reviewing and updating fire safety policies and procedures to address emerging risks and incorporate best practices.
- Hospitals must regularly conduct electrical load audits, particularly when adding new equipment or converting spaces into ICUs.
- They must strictly adhere to regulatory requirements and obtain valid fire No-Objection Certificates (NOCs) from their respective state fire departments.
- Implementing strict no-smoking policies and controls on heat sources in areas with oxygen tanks or piped oxygen. Signage should clearly mark these areas, and staff should be trained on the risks associated with high-oxygen environments.

Ministry of Housing and Urban Affairs (MOHUA) Recommendations

The MOHUA has also issued recommendations for fire safety during the construction of hospitals. These include:

- Prohibition on the usage of combustible/flammable material for partitioning, wall panelling, false ceiling etc. In addition, any material that releases toxic gases/smoke must also not be used if involved in the fire.
- All hospital buildings of 15 m. and above or having a number of beds exceeding 100 need to appoint a qualified fire officer
- Electric distribution cables/wiring must be laid in a separate duct and should be sealed on every floor with non-combustible material. The fire resistance of the duct must be similar to that of the material.
- The ducting should be constructed of metal in accordance with BIS 655:1963
- The material used for insulating the duct system (inside or outside) should be flame resistant (IS 4355: 1977) and non-conductor of heat
- Boilers must be installed in a fire-resistant room of 4 hours fire resistance rating
- Welding or use of a blow torch must only be done under strict supervision. It must be in full conformity with the requirements laid down in IS: 3016-1966 code of practice for fire precautions in welding and cutting operations.

Fire Safety Recommendations

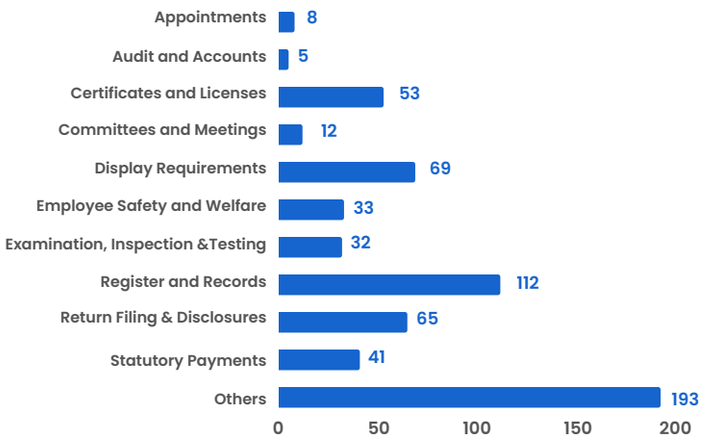
The NABH has also published recommendations for fire safety. These include:

- Periodic fire drills and training to help the hospital staff to understand their roles and responsibilities during a fire emergency
- Regular inspection of fire exits
- The location of the firefighting equipment should be identified, and the building occupants should be aware of the location of the fire protection equipment, manual call points, smoke detectors
- An assembly point should be designated outside the hospital building with a clear path to reach the assembly point.
- Regular inspection of the Firefighting system and the fire alarm system
- Laboratory experiments or pressure vessels should not be left unattended
- Adequate housekeeping should be ensured in the pharmacy and fire extinguishers should be provided to deal with a fire eventuality
- Fire retardant material must be used for the curtains, bedsheets, ceiling and wall claddings
- Regular third-party fire safety audits must be conducted for the hospital buildings
- Regular inspection of electrical points, circuit boards, and wiring

Types of Compliances

Having looked at the different categories of compliances, this section will look at the broad types in which such compliances are typically classified.

Figure 6: Type-wise Compliances for a hospital*



APPOINTMENTS

Under the Companies Act, 2013, and the Companies (Audit and Auditors) Rules, 2014, hospitals must file a Notice of Appointment of Auditor in Form ADT-1. Additionally, eligible companies must appoint a Cost Auditor as stipulated by the Companies (Cost Records and Audit) Rules, 2014, and file a notice of this appointment with the Central Government in Form CRA2. They are also required to appoint a Radiological Safety Officer to ensure compliance with radiation safety standards under the Atomic Energy Act, 1962, and the Atomic Energy (Radiation Protection) Rules, 2004.

Furthermore, they are mandated under the Pharmacy Act, 1948, and the Pharmacy Practice Regulations, 2015, to appoint registered pharmacists to oversee the dispensing of medications and ensure adherence to pharmaceutical standards.

AUDIT AND ACCOUNTS

Different auditing requirements are required for hospitals under different laws. For instance, under Information Technology Act 2000 and Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011, the hospital must conduct an annual audit of reasonable security practices and procedures. The Maharashtra Fire Prevention and Life Safety Measures (Amendment) Act, 2023, added Section 45A which added the obligation for a Fire & Life safety audit of buildings once in two years.

As per the Secretarial Standard on General Meetings (SS-2) approved by the Central Government, any adverse qualifications, observations or comments on the financial transactions that are mentioned in the auditor's report must be read out at the Annual General Meeting.

CERTIFICATES AND LICENSES

The Maharashtra Nursing Homes Registration Act, 1949, and Maharashtra Nursing Homes Registration Rules, 1973, require hospitals to obtain a renewed certificate of registration in Form C from the local supervising authority. Additionally, hospitals must obtain a certificate of registration in Form B from the appropriate authority under the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994, and its rules.

Under the Indian Medical Council Act, 1956, and TB Notification Guidance, 2012, hospitals must register for TB notification in Form Annexure I with the Nodal Officer for TB Notification in the district. Furthermore, under the Drugs and Cosmetics Act, 1940, and Drugs and Cosmetics Rules, 1945, hospitals must renew their license to sell, stock, exhibit, offer for sale, or distribute drugs other than those specified in Schedule C, C1, and X. Compliance with these regulations ensures proper management of controlled substances, registration of medical facilities, notification of communicable diseases, and adherence to pharmaceutical distribution standards.

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COMMITTEES AND MEETINGS

Hospitals must institute committees and ensure that mandatory meetings are being convened. Under the Maharashtra Shops and Establishments (Regulation of Employment and Conditions of Service) Act, 2017, and its rules, they must constitute a Health, Safety, and Welfare Committee to oversee and ensure the well-being of employees. The Sexual Harassment of Women at Workplace (Prevention, Prohibition & Redressal) Act, 2013, mandates the reconstitution of the internal committee every three years to address and prevent sexual harassment.

Under the Environment (Protection) Act, 1986, and the Bio-Medical Waste Management Rules, 2016, hospitals are required to hold meetings of a dedicated committee to review activities related to bio-medical waste management. The Companies Act, 2013, along with the Companies (Management and Administration) Rules, 2014, requires holding an Annual General Meeting to discuss and review the company's annual performance and strategies. Additionally, under the Companies (Meetings of Board and its Powers) Rules, 2014, regular meetings of the Board of Directors must be conducted to oversee and guide the company's operations and decision-making processes.

DISPLAY REQUIREMENTS

Hospitals are required to adhere to several display requirements. Under the Atomic Energy Act, 1962, and the Atomic Energy (Radiation Protection) Rules, 2004, they are required to display radiation symbols or warning signs to indicate areas where radiation is used, ensuring safety and awareness among staff and patients. Under the Medical Termination of Pregnancy Act, 1971, and the Medical Termination of Pregnancy Rules, 2003, hospitals must display the certificate of approval for conducting medical terminations of pregnancy, confirming that they are authorized to perform such procedures. Additionally, under the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994, and its rules, hospitals must display notices prohibiting the disclosure of the sex of the fetus to prevent sex-selective practices.

Furthermore, under the Indian Medical Council Act, 1956, and the Indian Medical Council (Professional Conduct, Etiquette, and Ethics) Regulations, 2002, physicians are required to display their registration numbers in their clinics and on all prescriptions, certificates, and money receipts.

A significant number of display requirements are contained under labour laws. For example, laws such as the Child and Adolescent Labour (Prohibition and Regulation) Act, 1986, Employees Compensation Act, 1923, Maternity Benefit Act, 1961, Minimum Wages Act, 1948 and Payment of Gratuity Act, 1972 make it mandatory for an employer to display an abstract of the Act and Rules within the establishment. The Minimum Wages Act, 1948 and Contract Labour (Regulation and Abolition) Act, 1970 impose additional requirements such as displaying notice regarding the rates of wages, dates of payment of wages and rest days.

The Rights of Persons with Disabilities Act, 2016 requires employers to display an equal opportunity policy for disabled persons. The Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act, 2013 mandates the display of a flow chart of the sexual harassment complaint redressal process and the names and contact details of the members of the Internal Committee. Under the Cigarette and Other Tobacco Products (Prohibition of Advertisement and the Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003 & Prohibition of Smoking in Public Places Rules, 2008, stores are required to display a "No Smoking Area" sign at the public entrance.

EMPLOYEE SAFETY AND WELFARE

Several provisions have been made under the Minimum Wages Act, 1948 such as providing explanations about proposed fines or deductions, intimating the amount of fines or deductions and giving wages for rest days in case the employee was given a substituted rest day.

Under the Maternity Benefit Act, 1961, a hospital employing 50 or more employees must provide crèche facilities with all necessary arrangements and supplies and allow 4 crèche visits per day to women employees. It must also permit 2 nursing breaks of 5-15 minutes until the child attains the age of 15 months.

The Sexual Harassment of Women at Workplace (Prevention, Prohibition & Redressal) Act, 2013 makes provisions regarding skill-building programmes and seminars for the Internal Committee members, dissemination of internal policy for promoting gender-sensitive safe spaces and awareness workshops for employees.

EXAMINATION, INSPECTION AND TESTING

Certain requirements for examination, inspection and testing have been prescribed under the Bureau of Indian Standards Act, 2016. These include monthly inspections and testing of all mechanical parts, extinguishing media and expelling means of fire extinguishers to be carried out by properly trained and competent personnel. In premises where Diesel Generator (DG) sets are used, the Environment (Protection) Act, 1986 mandates a proper routine to be set to prevent the deterioration of noise levels.

Under labour laws such as the Minimum Wages Act, 1948 and Employees State Insurance Act, 1948, every employer is required to maintain an inspection book. Under EHS-related compliances such as the Bureau of Indian Standards Act, 2016 read with Indian Standard - Selection, Installation and Maintenance of First-Aid Fire Extinguishers - Code of Practice, a company is required to paste inspection cards on the body of fire extinguishers and maintain records of inspection and testing of the fire extinguishers

Hospitals are required to conduct general medical examination for its workers every 3 years and maintain surveillance of its workers involved with radioactive substances under the Atomic Energy Act, 1962 and Atomic Energy (Radiation Protection) Rules, 2004.

REGISTER AND RECORDS

There are a variety of compliances for registers and records under various laws. The Contract Labour (Regulation and Abolition) Act, 1970 requires employers to maintain a register of contractors. The Payment of Bonus Act, 1965 requires maintaining a register showing the computation of allocable surplus, set-on and set-off of allocable surplus and bonus payable. The Minimum Wages Act, 1948 lays down compliances for maintaining an inspection book and a register of wages, fines and overtime. Under the Environment (Protection) Act, 1986 and Bio-Medical Waste Management Rules, 2016, every occupier is required to maintain and update on a day-to-day basis the bio-medical waste management register.

Under the Medical Termination of Pregnancy Act, 1971, and the Medical Termination of Pregnancy Rules, 2003, they are required to maintain an Admission Register in Form III. This register is crucial for documenting all medical terminations of pregnancy performed within the facility. Additionally, under the Indian Medical Council Act, 1956, and the Indian Medical Council (Professional Conduct, Etiquette, and Ethics) Regulations, 2002, hospitals must maintain comprehensive patient records. These records include case histories, investigation reports, images, and other relevant medical documentation. The regulations also mandate the maintenance of prescription records for in-person consultations, ensuring that all medical advice and treatments are accurately recorded. Compliance with these regulations ensures that hospitals maintain high standards of patient care, legal accountability, and ethical medical practice.

RETURN FILING AND DISCLOSURES

The compliances for return filing, disclosures and intimations are primarily contained in the labour laws. For instance, annual returns must be filed under the Employees' Compensation Act, 1923, Maternity Benefit Act, 1961, Minimum Wages Act, 1948 Payment of Bonus Act, 1965, Contract Labour (Regulation and Abolition) Act, 1970 and quarterly returns under the Employment Exchange (Compulsory Notification of Vacancies) Act, 1959.

Additionally, under the Indian Medical Council Act, 1956, and the Maternal Death Review Guidelines, facilities are required to file Annexure 1 in the case of maternal deaths. This ensures proper documentation and review of such incidents to improve maternal health outcomes. Under the Narcotic Drugs and Psychotropic Substances Act, 1985, and the Maharashtra Narcotic Drugs and Psychotropic Substances Rules, 1985, hospitals must annually furnish information regarding the purchase and consumption of manufactured drugs to the licensing authority.

Under the Environment (Protection) Act, 1986, and the Bio-Medical Waste Management Rules, 2016, hospitals are also required to provide information about all accidents and the remedial steps taken in their Annual Report. As per the Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act, 2013, the Internal Committee must prepare and submit a report to the employer and district officer. The Collection of Statistics Act, 2008 and Collection of Statistics (Central) Rules, 1959 mandate furnishing returns in the prescribed format to the Statistics Authority.

STATUTORY PAYMENTS

Under the Employees' State Insurance Act, 1948, an employer must make monthly contributions in respect of an employee to the Employees' State Insurance Corporation via electronic mode. Certain statutory payments are also prescribed under the Minimum Wages Act, 1948, Payments of Bonus Act, 1965 and Apprentices Act, 1961.

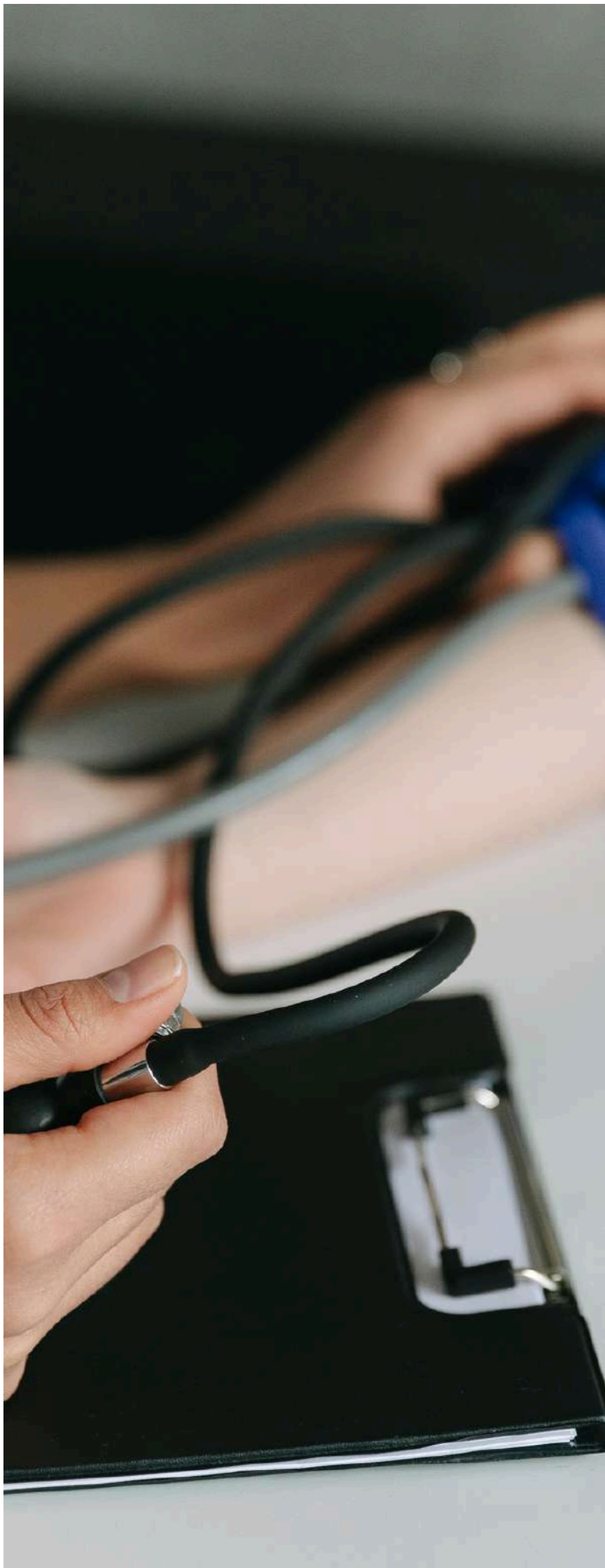
Various municipal and state laws also prescribe statutory payments to be made for property tax, advertising permit fees, Labour Welfare Board contributions and electricity consumption tax, among others.

Instances of Non-Compliance

Major instances of non-compliance in healthcare institutions revolve around contravention of standards of care, requirement of appropriate approvals, disposal of bio-medical waste and fire prevention.

A number of hospitals have been fined for non-display of hospital charges to the public. They have indulged in unregistered usage of medical devices such as ultrasound machines along with improper storage. There have been instances of improper registration of pregnant women before conducting sonography and not maintaining proper records of tests. Hospitals have also been found to violate procedures related to disposal of bio-medical waste. These actions violate the regulations laid down under Pre-Conception and Pre-Natal Diagnostic Techniques Act, 1994, Assisted Reproductive Technology (Regulation) Act, 2021, the Surrogacy (Regulation) Act, 2021, and Bio-Medical Waste Management Rules, 2016.

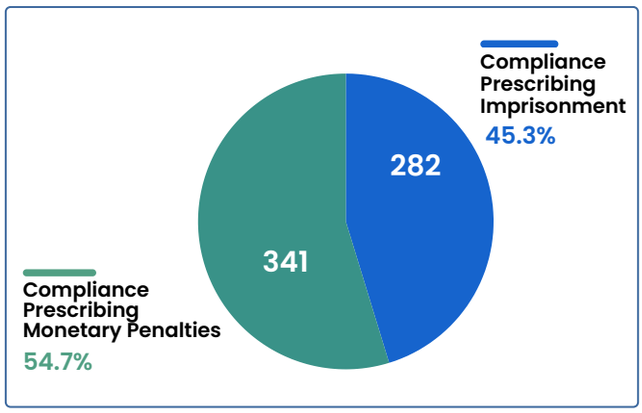
There are also violations related to Maharashtra Nursing Homes Registration Act 1949 and Medical Termination of Pregnancy (MTP) Act, 2021. Violations include employing unregistered nurses, non-maintenance of proper medical records, non-display of shift times, to name a few. Furthermore, several hospitals have been also found to have not maintained grievance redressal records and not even appointed a grievance redressal officer. Other violations relate to maintaining a hygienic environment within the hospital premises. A significant number of instances involved non-display of qualification certificates of doctors and healthcare professionals.



State of Criminalisation

A thorough review of India's business laws reveals that imprisonment has been used as a tool of control against entrepreneurs over the years. The report titled Jailed for Doing Business, co-authored by Gautam Chikermane and Rishi Agrawal, uncovers the nature and extent of the risks of imprisonment faced by entrepreneurs in the country. Of the 1,536 laws that govern doing business in India, more than half (54.9%) carry imprisonment clauses. Among the 69,233 compliances contained in these laws, two out of every five (37.7%) prescribe jail terms for non-compliance. The monogram highlights that a sizable portion of these clauses criminalises procedural violations and technical lapses rather than serious offences involving willful harm. It illustrates that in many cases, there is an equivalence between punishment for minor errors by entrepreneurs and for death due to negligence under the Indian Penal Code, 1860. Resultantly, the current business environment reflects a sense of distrust and hostility towards companies and raises barriers to the seamless flow of innovation, wealth and jobs in the economy.

Figure 7: Imprisonment clauses as a share of total compliances for a Hospital*



With this basic premise of the monograph, Teamlease Regtech has compiled data on the imprisonment clauses facing hospitals. A single entity, 50-bed hospital with a diagnostic centre, radiology, pathology lab, and pharmacy with a corporate office in a single state deals with 623 compliances in a year. Among them, 282 (~45%) compliances contain imprisonment clauses. 73% (206) of these clauses are contained in Union laws while the rest are within State laws.

Classifying these across the seven categories of compliance, we find that EHS laws account for one-third of all the obligations prescribing jail terms.

Figure 8: Imprisonment Clauses across Levels of Compliance

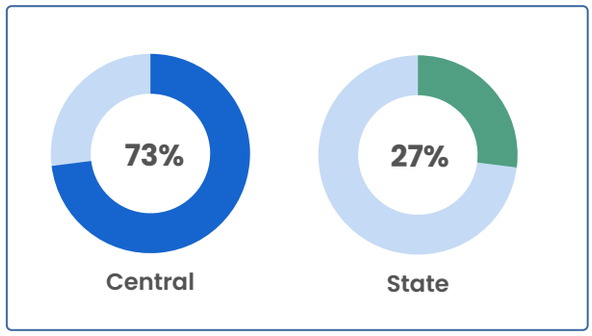
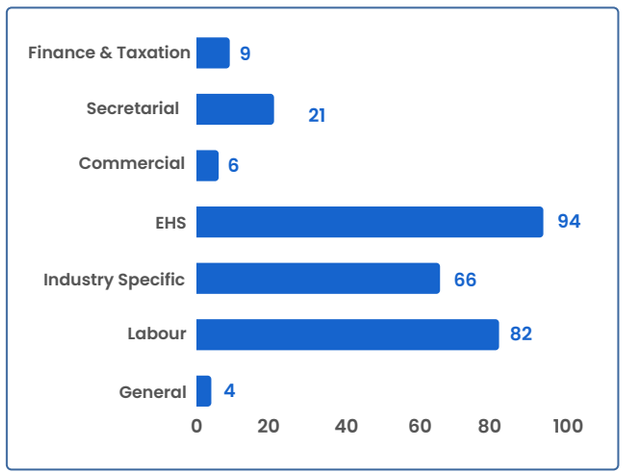


Figure 9: Distribution of imprisonment clauses across compliance categories



As evidenced by the data, the implications of non-compliance can be severe. Hence, hospitals must focus on establishing strong control over their compliance obligations. Staying on top of the regulatory changes, filings, permissions, and approvals, among others, must assume priority for the institution.

**Single entity, 50-bed hospital with a diagnostic centre, radiology, pathology lab, and pharmacy with a corporate office operating in the Greater Mumbai*

Compliance Challenges for Hospitals

Between the Indian Medical Council Act, 1956 and its subordinate regulations, and the Atomic Energy Act, 1962 and Radiation Surveillance Procedures for Medical Application of Radiation, 1989, compliance officers in hospitals need to comply with tens of acts and hundreds of rules, depending on the size of the hospital. Depending on the nature of care provided by the institution, there is also requirement to adhere by the compliances under Indian Medical Council Act, 1956, Pharmacy Act, 1948 etc.and their subordinate regulations.

Given below are some of the major compliance challenges faced by the healthcare sector. Many of these are in congruence with a larger survey of clients conducted by TeamLease Regtech on regulatory complexity and the Ease of Doing Business in India.

LACK OF AN ACCURATE LIST OF APPLICABLE COMPLIANCES

A single-entity 50-bed hospital with a diagnostic centre, radiology, pathology lab, and pharmacy with a corporate office in a single state needs to deal with 623 unique compliances in a year. As the hospital increases its size, scale, and geographical footprint, the number of compliances multiply. These compliances are at three levels - centre, state and local. In addition, they are spread across seven compliance categories - labour, environment, health and safety (EHS), finance and taxation, commercial, secretarial, industry-specific and general. Identification of the applicable compliances for a healthcare institution requires deep expertise.

The applicability of compliance also varies based on the location of the hospital, no. of beds, nature of medical care provided by it, diagnostic and laboratory facilities available and use of specific equipment (such as boilers, pressure vessels, weights and measures, heat exchangers, fire extinguishers, centrifuges, etc.). In addition, there are challenges pertaining to the ever-changing threshold quantities and its notification to the concerned authority. Most hospitals in India find it highly challenging to track compliance for such a broad spectrum of regulations.

Apart from these, hospitals are also expected to adhere to the BIS and ISO Standards. On top of this, laws and rules constantly undergo amendments, leading to periodic changes in applicability and compliance obligations. The lack of an accurate list of this diverse range of laws, rules and regulations can make compliance an extremely challenging task for hospitals.

FLUID REGULATORY ENVIRONMENT

India's regulatory environment is fluid. Just in FY2023-24, there were close to 8,000 regulatory updates published on the 2,233 websites of union, state and local government websites via notifications, gazettes, circulars, ordinances, master circulars, and press releases, among others. These updates typically lead to changes in forms, dates, timelines, frequencies, fines, interest rate calculations, applicability threshold values, and letters of the law, among others. Since these changes are often applicable almost immediately, they require a time-sensitive interpretation and implementation. There were over 4,000 regulatory updates that affected in the healthcare industry in the last financial year. Among these, more than 2,200 were issued by Central level authorities.

Unfortunately, there is no centralised repository of regulatory updates that provides national, real-time, comprehensive and personalised information on all changes that affect the compliance burden. As a result, the compliance officers are often expected to periodically visit literally hundreds of websites to ensure that they are not missing any critical updates.

STRICT LIABILITY IMPLICATIONS

Healthcare is a critical sector that involves the health and safety of patients. As such, the doctrine of strict liability becomes applicable to healthcare institutions to ensure a high standard of care and safety of the patients. Under the Medical Termination of Pregnancy Act, 1971, and the Medical Termination of Pregnancy Rules, 2003, they must submit an application for approval of the place for medical termination of pregnancy in Form A.

Additionally, under the Atomic Energy Act, 1962, and the guidelines for Radiation Safety in the Manufacture, Supply, and Use of Medical Diagnostic X-Ray Equipment, hospitals must provide structural shielding in X-ray rooms to prevent radiation exposure. Servicing of X-ray equipment must be carried out by agencies authorized by the regulatory body to ensure safety and compliance with radiation standards. The Pharmacy Act, 1948, and the Pharmacy Practice Regulations, 2015, prohibit the appointment of unregistered or unlisted attendants, ensuring that only qualified personnel handle pharmaceutical tasks. Furthermore, hospitals must maintain records of drugs administered to patients under the same act and regulations.

Considering the diverse range of these compliance requirements and the lack of any comprehensive checklist in this regard, hospitals must always be alert as to their compliance with these requirements. In cases of poor compliance, strict liability can be imposed on hospitals by the relevant authorities, which can likely result in both criminal as well as financial penalties.

POOR TRACKING AND MANAGEMENT OF APPLICABLE LICENCES

A typical healthcare institution in India deals with tens if not hundreds of licenses. These include medical licenses, shop and establishment registrations, certification and standardisation requirements by Atomic Energy Regulatory Board (AERB), gas cylinder and boiler authorisations, consent to operate, fire safety NOCs, hazardous and biomedical waste authorisations, among many others. An illustrative list of licenses has been provided in Table 2.

- Issue Date
- Expiry Date
- Categorisation of Industry (Red, Orange, Green, White)
- Conditions of License (Client Specific)
- Days for application for next renewal

Licences, registrations, permissions, consent orders and NOCs need to be tracked meticulously to ensure that they are in good order, failing which, there are serious business consequences. Most organisations lack robust processes that provide adequate assurance for statutory licence management.

POOR TRACKING OF EVENT-BASED COMPLIANCES

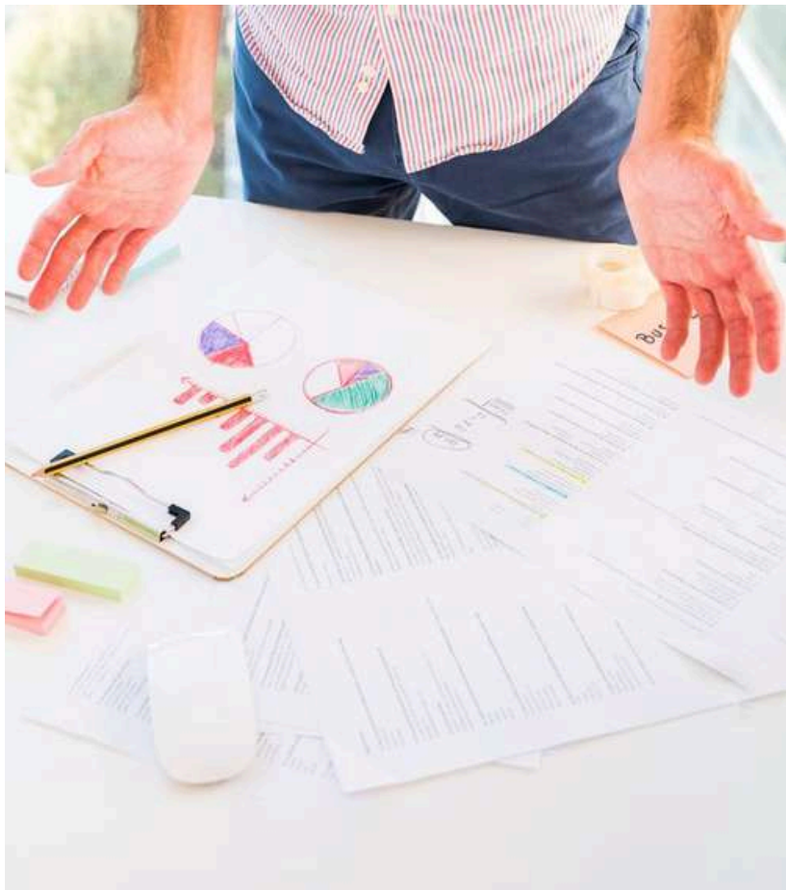
There are many instances where the applicability of licenses and compliances changes based on the occurrence of specific business events. As a result, the compliance officer needs to keep his eyes peeled to identify such occurrences, be ready to interpret their impact on the organisation's compliance obligations and implement a quick and comprehensive response. A hospital also deals with various kinds of audits such as safety audits, environmental audits, and fire drills. Furthermore, compliance teams must keep track of periodic medical examinations of its workers involved with radioactive machinery and maintain relevant medical records. Hospitals are also required to conduct committee meetings to review waste management activities. For instance, bio-hazardous waste is constantly generated in hospitals. This waste needs to be disposed off with a significant amount of paperwork and processes involved. Employers often struggle to keep up with these requirements, leading to lapses, delays and defaults.

POOR TRACKING OF ONGOING COMPLIANCES

A typical hospital deals with a large number of compliances that are ongoing in nature. These include displays (licenses, registrations, abstracts of legislations, employee-related social security-based displays, labelling, storage conditions, emergency planning, no smoking, fire exits, danger signs, GST Number, abstract for the prohibition of employment of child labour, etc.), maintenance of registers & records, and ensuring hygienic and sanitary conditions. These ongoing compliances when not adhered can result in a high cost of poor compliance.

For instance, the company must maintain a variety of registers that must be current at all points of time. These include leave and attendance, wage registers, temperature registers, records of disposal of waste, admission registers, patient records, prescription records, and records of disposal of bio-medical waste, among at least 40 other unique registers in various formats.

Creating, maintaining, reviewing and certifying that these registers are in compliance with the law of the land is the responsibility of different people across the organisation. Unfortunately, there are no enterprise processes to track and maintain the digital copies of these registers and obtain periodic self-certification from the relevant stakeholders.



LACK OF AWARENESS AT MANAGEMENT LEVEL

Based on a recent survey conducted by TeamLease RegTech, it was discovered that the key managerial personnel (KMP) in Indian hospitals have a poor understanding of compliance obligations in over 75% of the instances.

As a result, they are often unpleasantly surprised in instances of show cause notices, financial penalties, cancelled licences, revoked permissions and leaked revenue. Under the survey, most executives were found to have a very poor handle on the status of key compliances, dates, documentation and residual risk of non-compliance.

ANECDOTAL COMPLIANCE CERTIFICATION

The Companies Act, 2013 mandates the issuance of compliance certificates to the Board. Since the organisation is lacking in technology-based tracking systems, the compliance officer has no choice but to prepare the statutory compliance certificates manually.

These certificates often miss key information such as the specific data on an instance of non-compliance, delayed filings and the residual risk of poor compliance. In such instances, the board is often flying blind as they do not have any framework to establish the level of compliance in the company.

MANUAL, PAPER BASED AND PEOPLE DEPENDENT COMPLIANCE

A typical mid-sized hospital deals with a few thousand compliances in a year. There are at least 50-100 people in different departments (human resources, finance and taxation, company secretarial, administration, environment, health and safety, warehouse, research and development, etc.) directly involved in day-to-day compliance functions.

Unfortunately, while compliance is a key binding constraint in an organisation's growth, a number of Indian organisations are yet to adopt technology platforms for transparent and accountable compliance programs. The compliance officers often use spreadsheets to track status manually. Resultantly, there can be many instances involving inadvertent misses, delays, lapses, defaults, expired licences and missed legal updates. Hence, it is not uncommon to see them firefighting and highly stressed during regulatory audits.

Recommendations for Enabling Ease of Compliance

In India, employer compliance requires a complete overhaul. With the regulatory framework of the 19th and 20th centuries, entrepreneurs have been unable to compete in the 21st century. Businesses can take a number of actions to improve compliance management within their establishments. Some of the low-hanging fruits are briefly highlighted below:

CREATING A CULTURE OF COMPLIANCES

The primary factor influencing any organisation is the "Tone at the Top." A "Zero Tolerance" policy on compliance from the top management needs to be evident at all organisational levels. A strong compliance management programme is also implemented at the organisational level by the compliance officers with the assistance of top management, which is involved in the review of compliance statuses.

ADOPTING DIGITAL SOLUTIONS

Technology is the key to most of the problem statements, and compliance is not untouched. Several RegTech players have emerged who have invested heavily in technology solutions to support organisations in effectively tracking and managing their compliance programs. Additionally, a few RegTech players have also introduced automation layers to reduce manual dependency and intervention and reduce the overall cost of compliance for any organisation. Enterprises must consider adopting solutions that can either automate the process of overall management or can also automate the compliance document generation process as well.

Rationalisation

- There is a lot of duplication, redundancy and overlap across compliances. It is recommended that a detailed analysis of such opportunities be conducted. The list should be classified into items that can be executed by executive order and those requiring legislative change. Based on an initial assessment, at least 20 to 30% of the compliances can be reduced without affecting the outcomes

- The current process of inspections is ad-hoc, manual, paper-based and people-dependent. There is limited transparency and accountability. The inspection process should be reviewed and a risk-based, faceless, presence-less, cashless inspection process should be implemented.

- Opportunities for self-certification and third-party inspections should be rolled out.

- Digital interfaces (new license applications/ renewals/ return filings/ requests for inspection etc) should be identified and developed.

Digitisation

- There should be a single digital portal for centralised publishing of all regulatory updates across various departments and ministries and at all governance levels. The portal should be a technology utility that should be extended to all relevant stakeholders. It should provide the capability to subscribe to automated alerts based on filters such as type, industry, location and compliance category, among others.

- A digital platform to automate the creation of all regulatory records for compliance should be created. It should also facilitate the safe storage and authentication of such records.

Decriminalisation

- Criminal penalties in business laws should be used with extreme restraint. Misdemeanours such as procedural lapses and technical non-compliances should be punished with financial penalties only whereas criminal penalties should be retained only for serious crimes involving intentional harm.

- A general and indicative set of standards should be adopted to guide lawmakers, executive authorities and regulators in making laws, rules and regulations. Such standards should include principles of necessity and proportionality.

- All imprisonment clauses must go through legislative scrutiny at least once in five years. For this, sunset clauses can be introduced in the legislative process to ensure either the renewal or termination of imprisonment clauses depending on their need and relevance in light of the evolving business climate.

TeamLease RegTech®
Helping India Comply

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