



# Secretarial Audit for Health Care Industry

The Supervision and regulation of the quality of services provided by the health care delivery system to the people by both public and private sectors has largely remained a contentious and unresolved issue. The current structure of the health care delivery system does not provide enough incentives for improvements in efficiency. The Private sector health care delivery system in India has remained largely unregulated and uncontrolled. Problems range from inadequate and inappropriate treatment, excessive use of higher technologies, and wasting of scarce resources to serious problems of medical mal practices and negligence.



Despite many legislatures including state legislatures and many central laws enacted for regulating the Health Care Industry the general perception is current regulatory process for health care providers in India is inadequate or not responsive to ensure health care services of acceptable quality and prevention of negligence.

In spite of all regulatory issues & other problems, The Indian Healthcare sector is emerging as one of the fast-growing service sectors in India, contributing 6 – 7 percent to the country's Growth Domestic Product (GDP). According to 2001 population norms, there was still a shortage of 4,477 primary healthcare centers and 2,337 community healthcare centers and India would require 1.75 million beds by 2025. Over 6800 more hospitals are needed in India to provide basic health facilities to people in rural areas.

In this backdrop let us see the plethora of laws that have been enacted for the Health Care Industry in India & their compliance.

## TYPES OF HEALTH CARE INDUSTRY

### Mobile Health – Tele Medicine - Possible Services

1. Division of hospital rendering tele medicine
2. services ( tele radiology)
3. Standalone tele radiology companies
4. Service providers companies ( IT)
5. Value added services
6. Tele monitoring / health monitoring

### Preventive & Wellness Care Centers – Possible Services

1. Nutraceuticals and herbals
2. Dietary supplement companies
3. Organic foods and health supplements

### Day Care / Short Stay Centers – Possible Services

1. Surgery / specific discipline
2. Critical Care Centers
3. Emergency Operation Rooms and recovery centers
4. Basic recovery centers
5. Ambulance services

### Support Services Centers – Possible Services

1. Nursing
2. Para medics services
3. Hospital Management Services
4. Medical tourism companies
5. Hospital housekeeping
6. Ambulance services
7. Low cost health services
8. Equipment leasing / services

### Pain Clinics – Possible Services

Advanced pain relieving centers

### Geriatric Care Centers – Possible Services

1. General care
2. Hospice centers

### Physical Therapy Centers – Possible Services

1. Post trauma
2. Post-surgery
3. Along with other support services

### General Diagnostics Centers – Possible Services

1. Neuro-physiology
2. Advanced Radiology
3. Hematology and Advanced Histopathology

Whatever may be the type of Industry once recognized as a medical center OR a Hospital a plethora of acts & Licenses become applicable.

### **SECRETARIAL AUDIT: WHAT IT MEANS?**

Secretarial Audit' is a process to check compliances made by the Company under Corporate Law & other laws, rules, regulations, procedures etc. It is a mechanism to monitor compliance with the requirements of stated laws and processes. Secretarial Audit gives comfort to the regulators, stakeholders and management, that company has disciplined approach to evaluate and improve effectiveness of risk management, control, and governance

The Secretarial Audit Report must be in Form MR -3 (which has been prescribed in the Companies Act, 2013 and a specific format has been issued). Thus the scope of Secretarial audit is not limited to the corporate laws applicable to company but it extends to **“all laws applicable to Company”**.

What should be reported under this section is a question of debate, what Laws are applicable to the respective company etc... Reporting on compliance of 'Other laws as may be applicable specifically to the company' shall as per the guidelines issued by the ICSI include all the laws which are applicable to specific industry for example; for Banks- all laws applicable to Banking Industry; for insurance company-all laws applicable to insurance industry; likewise for a company in petroleum sector- all laws applicable to petroleum industry; similarly for companies in pharmaceutical sector, cement industry etc. Therefore, all laws applicable to a Health Care Industry shall be examined by the Secretarial Auditor.

***We shall discuss on the various legislations applicable through an audit check list in the next edition in Part 2.***





# Secretarial Audit for Health Care Industry

Last month we discussed on the background and issues in the Health Care Industry. We observed that despite many legislatures including state legislatures and many central laws enacted for regulating the Health Care Industry the general perception is current regulatory process for health care providers in India is inadequate or not responsive to ensure health care services of acceptable quality and prevention of negligence. However, The Indian Healthcare sector is emerging as one of the fast-growing service sectors in India, contributing 6 – 7 percent to the country's Growth Domestic Product (GDP). We listed out types of Health Care Industry and understood that this sector has to comply with plethora of acts & Licenses.



Secretarial Audit' is a process to check compliances made by the Company under Corporate Law & other laws, rules, regulations, procedures etc. Let us look at the legislations that are applicable to this industry.

SI #	LEGAL PROCESS & DOCUMENTATION	AUDIT REQUIREMENTS - RELEVANT PROVISIONS
1	PAN (Permanent Account #)	PAN Details - Income Tax Act
2	TAN (Tax Deduction Account #)	Income Tax Act
3	Lease Agreement for the Office Premises & register the same with stamp duty	May be own hospital premises OR Leased accommodation to verify relevant documents like lease agreements, Ownership Certificates, Stamp Duty Paid, Registered documents- Contract Act & Registration Act
4	Registration under the Shops & Commercial Establishments Act	Shops & Commercial Establishments Act, (may differ with each state) examine the certificates, annual returns filed under the act, Male, Female classification of employees, Number of employees, latest fee paid details
5	Registration under the Professional Tax Act	The Tax on Professions, Trades, Callings and Employment Act, (state specific) fees paid, registration certificates, Employee professional tax paid details, Annual Returns
6	Registration under the Provident Fund & Miscellaneous Provisions Act.	Employees Provident Fund and Miscellaneous Provisions Act 1952, Certificate of registration, Number of employees, PF Paid details, dates on which paid, Returns filed, Exemptions claimed if any with adequate proof
7	License under The Contract Labour (Regulation & Abolition) Act, 1970.	The Contract Labour (Regulation & Abolition) Act, 1970. Number of contract employees, names of the contractors, licenses of the contractors, ESI, PF paid details of the

		employees, salary sheets etc... to be verified
8	Registration under The Employees State Insurance Act	The Employees State Insurance Act (ESI), fees paid, certificates details, ESI paid details, ESI Cards for each employee, Hospital details where the employees may avail medical facilities, Returns Filed
9	Service Tax registration	Service Tax Act, applicability, ST Paid details, and returns filed. <u>We may rely on the Internal OR Statutory auditor certificates in this regard</u>
10	Registration under Karnataka Value Added Tax Act	Value Added Tax Act applicability, VAT Paid details, and returns filed. <u>We may rely on the Internal OR Statutory auditor certificates in this regard</u>
11	Registration under Pollution Control Laws	Pollution Control Act – Water, Air & Operating Licenses, effluent discharge, possible violations if any, consent orders, ETP Plants installations if required etc...
12	Registrations under Central Excise	Central Excise Act applicability, Tax Paid details, and returns filed. <u>We may rely on the Internal OR Statutory auditor certificates in this regard</u>
13	Registration under Narcotics & Psychotropic substances Act	License verification, compliance with the terms of the license, proper storage of Narcotic Substances, authorized purchase & usage etc..
14	Retail Drugs Licenses	Drugs & Cosmetics Act & Rules, proper licenses for running a Hospital Medical Store, appointment of a qualified pharmacists (diploma holder), proper storage of schedule H Drugs, proper compliance with the terms of the license, billings & issue of medicines, maintenance of registers under the Act, Medical store lease agreement if any
15	AERB - X-Ray, CT- Scan and other similar equipment.	Atomic Energy Act & Department of Atomic Energy. This required certain specific compliance and registrations
16.	Bio Medical Waste & Hazardous Storage Rules etc.. Authorization for operation of a facility for generation, collection, reception, storage, transportation, treatment and disposal of bio-medical wastes under Bio-Medical Waste (Management and Handling) Rules, 1998 of the Environmental Protection Act 1986 from the Pollution Control Board and corresponding compliances;	To dispose the water to proper & licensed contractors, to examine the licenses, agreements, discharge methods etc.
17	Labour Laws – Child Labour, Maternity Benefits, etc...	Child Labour must not be employed, We can take declaration from the management in this regard, Maternity benefits as per act, maintenance of all registers under the Act
18	Medical Termination of Pregnancies Act	Proper Licenses to be obtained, the doctors must not perform any abortions or pregnancy terminations without license
19	Explosives Act – For storage of Oxygen etc.	Examine the license, & place of storage. Must not be stored in the basements

20	Ministry of Health & Family Welfare	Registrations
21	Central Drugs Standard Control Organization (CDSCO) Narcotic Controls Bureau	Registrations
22	Fire safety Approvals;	Registrations
23	Municipal Trade license ( State Specific);	Registrations
24	Registration of facility with State Government / Authority as a private medical establishment (State Specific);	License verify
25	Registration under the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 and corresponding registration of ultrasound machine with appropriate authority under the Act;	License, Requirements, compliance with the terms of the license. Prohibition of Sex determination test etc.
26	Approval from State Food and Drug Administration to obtain and possess certain category of drugs for use on patients;	Especially Anesthetics, antibiotics, narcotics etc...
27	License to operate a blood bank from State Food and Drug Administration for procession of whole human Blood for preparation for sale or distribution of its components;	License to be examined
28	Permit for the purchase and possession of denatured spirit;	As this contains alcohol & spirits it falls under the state excise, license must be verified & examined under the act
29	Essential Commodities Act	Registration
30	IEC Code for Imports & Exports	If any equipments are to be imported

Major issues that can seriously impact functioning of the hospital are non-compliance with Preconception and Pre-Natal Diagnostic Techniques Act, 2003; Medical Termination of Pregnancy Act, 1971; Biomedical Waste Disposal, Drugs and Cosmetic Acts for pharmacy, Atomic Energy Regulatory Board and other environmental consent/s.

Healthcare sector is highly regulated in India. It is governed by various acts that cover establishment of hospitals, various services offered, medical professionals rendering services in the hospital as well as additional service offered by the hospital like cafeteria, pharmacy, ambulance etc.,

The company has to further comply with Companies Act, Secretarial Standards & Foreign Exchange Management Act for Influx of equity and funding options, SEBI Regulations & Listing Requirements & Securities Contract Regulation Act, Depositories Act etc.,

Health Care is a complex industry. Since Secretarial Audit is a huge responsibility of the Company Secretary in Practice, he must take the following precautions:

1. Obtain proper Information about the company
2. Understand the Business Model of the Company
3. Analyse the applicability of various laws
4. Have proper qualified man power
5. Make a through due diligence of the company
6. Obtain Management Representation from the company wherever required
7. Obtain Professional Indemnity Insurance
8. Take adequate precautions while conducting the Audit
9. Competency & Capacity Building

