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MEDICO-LEGAL ASPECTS IN AYUSH HOSPITALS AND HEALTH CARE CENTRES

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ABSTRACT

Medico-legal aspects are of utmost importance in Medical Profession for establishment of healthcare facility. AYUSH clinics and hospitals are also of no exception to this. AYUSH sector has grown to such an extent in recent years that there are more than 4000 AYUSH Hospitals and 6,00,000 AYUSH practitioners across the country. However, due to ignorance or unfamiliarity of laws pertaining to establishment, manpower, safe medication, patient care, environment etc. of AYUSH Hospitals and Health Care Centre's many practitioners face legal hassles and their precious professional time is compromised in rectifying the same. The article highlights the Laws, Acts, Rules and Regulations that the AYUSH practitioner should be aware of to be on the right side of the LAW.

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INTRODUCTION

Medical profession is regarded as a noble profession. In modern times, Indian doctors are at crossroads facing ethical and legal challenges in the practice of the profession. AYUSH doctors and hospitals are not an exception to this. Most of the times due to ignorance or lack of awareness practitioners end up in legal hassle. There are more than 60 statutory norms applicable to an AYUSH healthcare facility and also has some regional norms based on the location of the facility. Some of them have flexibility to accomplish them, however some are mandatory without which AYUSH practitioners are not allowed to venture into this noble profession. Delay in application may force one to pay fine with some legal obligations. It is hence very crucial to understand all the regulatory norms and establish a health facility and abide by it, to avoid legal implications. This topic does not deal with Medico Legal Cases which is totally an exhaustive area and an AYUSH practitioner should also have a comprehensive understanding. The focus of this article is to comprehend Laws, Acts, Rules, Regulations and Statutory Compliances required for AYUSH

Hospitals and Health Care centers. This subject is not dealt in our AYUSH Under-Graduate or Post Graduate curriculum for its practical applicability. It is in the best interest of AYUSH doctors to familiarize themselves with the basics of legal and statutory aspects of the AYUSH medical profession, the topic is dealt in present article. The awareness of these statutory compliances is also inevitable for achieving NABH Certification and Accreditations.

MATERIALS AND METHODS

A comprehensive search was done on Internet and on search engines like Google, PubMed and Other Government websites with Key words such as MEDICO-LEGAL ASPECTS including AYUSH and LAWS APPLICABLE TO AYUSH HOSPITALS. The results were summarized and presented as per the importance and need as understood by authors.

OBSERVATIONS

Presently, the operation of private AYUSH clinics or hospitals are being governed by the different National Laws and some State Laws. Results found in the search are enlisted in following table-

Table 1. Important Laws governing the AYUSH Establishments

Sl. No.	Laws & Regulations	Intended for

1	Laws governing the Commissioning of the AYUSH Hospital	Establishment of AYUSH Hospital
2	Laws governing the qualifications/practice and conduct of professionals	Professional Registration
3	Laws governing storage/sale of AUS&H drugs and safe medication	Medication
4	Laws governing the management of patients	Patient management
5	Laws governing environmental protection	Bio-medical waste and health hazards
6	Laws governing the employment of manpower in AYUSH Hospitals	Management of Medical, Paramedical and other staff
7	Regulations governing the business aspects of the AYUSH hospital	Governing the Hospital

1. Laws governing the Commissioning of the AYUSH Hospital

These laws make sure that the hospital facilities are created after due process of registration and are safe for the public. These laws include:

- a) Societies Registration Act, 1960¹ - The purposes of the act is to improve the legal conditions of societies established for the promotion of literature, science, or the fine arts and to give them a legal status.
- b) Companies Act 1956² - Registration with Ministry of Corporate Affairs
- c) Urban land Act 1976³ - The stated purpose of the law is "bringing about an equitable distribution of land in urban agglomerations to subserve the common good. (Currently repealed in Gujarat & Maharashtra)

d) National building code 2005(revised 2016)⁴

- National Building Code of India covers the detailed guidelines for construction, maintenance and fire safety of the structures. It is established by Bureau of Indian Standards and it is recommendatory. Design and Construction of Hospital is also explained in detail. Provision of Lifts depending on the number of floors and bed strength, number/width of stair cases and ramps to be provided in the hospital, height of the compound wall for securing the vulnerable patients in dealt in detail in National building code.

- e) A building permit from the local municipality
- f) Fire safety rules 1987 (NOC)⁵- An Act to make more effective provision for the fire

prevention and fire safety measures in certain buildings and premises. Provision of Detection, Alarm, Fire Extinguishment, Fire Prevention, Planning and Training programs for Isolation of Fire, Transfer of occupants to a place of comparative safety or evacuation of the occupants to achieve ultimate safety. All healthcare facilities shall be so designed, constructed, maintained and operated as to minimize the possibility of a Fire emergency requiring the evacuation of occupants, as safety of hospital occupants cannot be assured adequately by depending on evacuation alone. Hence measures shall be taken to limit the development and spread of a fire by providing appropriate arrangements within the hospital through adequate staffing, careful development of operative and maintenance procedures.

- g) Electricity Rules 1956⁶ - All electric supply lines and apparatus shall be sufficient in power and size and of sufficient - mechanical strength for the work they may be required to do, and, so far as is shall be constructed, installed, protected, worked, and maintained in accordance with the standards of the Indian Standards Institution so as to prevent danger.
- h) Radiation protection certificate for radiology dept from AERB - The Atomic Energy (Radiation Protection) Rules, 2004

[AE(RP)R-2004],⁷ promulgated under the Atomic Energy Act, 1962,⁸ provides the legal framework for the safe handling of radiation generating equipment (in this context - X-ray equipment). As per Rule 3 of AE(RP)R-2004 it is mandatory for all the manufacturers/Suppliers/Users of x-ray equipment, to obtain requisite 'Licence ' from AERB for carrying out any of the above activities. Layout approval for radiation departments area – If the hospital uses **radiology** or radiation therapy departments the layout and design of the area must be approved by AERB.

- i) Permit for Diesel Storage - If the hospital stores large quantity of petroleum product such as Diesel for using in Diesel generator a permit must be obtained from Controller of explosives, under Petroleum act 1934.⁹ The permit is required generally if the storage required is in excess of 30 liters.
- j) Permit to store LPG cylinder– If the hospital stores large quantity of LPG cylinder for use in hospital's, Panchakarma and kitchen or any other purpose, it shall take a permit from Controller of Explosives under Petroleum act, 1934.⁹
- k) Certificate for using Boilers under the Indian Boilers act, 1923¹⁰ – If the hospital uses large Boilers, a certificate for its use must be obtained under Indian Boiler's act from Boiler inspectors. The certificate is generally

issued for a period of 3 years and must be renewed.

l) License for operating lift – If the hospital's building has lifts installed in it, a certificate must be obtained for operating the same. The certificate is issued after inspection by Lift safety inspector, who assess if the requirements stated under Lifts and Escalator acts act

m) Indian Telegraph Act of 1885¹¹ - The Indian Telegraph Act, 1885 is the enabling legislation in India which governs the use of wired and wireless telegraphy, telephones, teletype, radio communications and digital data communications.

n) Clinical Establishments Act, 2010¹² - The Clinical Establishments (Registration and Regulation) Act, 2010 is an Act of the Parliament of India. It seeks to regulate all clinical establishments in India. The Act requires all clinical establishments to register themselves and provides a set of standard treatment guidelines for common diseases and conditions. The state governments must adopt the law by passing a resolution in the legislative assemblies. As of March 2018, the following states have adopted it: Himachal Pradesh, Mizoram, Sikkim, Bihar, Rajasthan, Uttar Pradesh, Uttarakhand, Jharkhand, Assam, Haryana. However, not all of these

states have made any clear provisions to implement the Act.

o) The Registration Act, 1908 - An Act to consolidate the enactments relating to the Registration of Documents.

p) Food & Beverages license - The Food Standards and Safety Authority of India (FSSAI) is the supreme authority which is responsible for regulating and supervising the food safety. So, it is mandatory to take FSSAI Basic Registration as per the law.

2. Laws governing the qualifications/practice and conduct of AYUSH professionals: -

These laws make sure that the employees employed in the hospital are qualified and authorized to perform their jobs. These laws include erstwhile Central Council of Indian Medicine's Indian Medicine Central Council Act, 1970 (Chapter Iv-Central Register)

Practitioners of Indian Medicine (Standards of Professional Conduct, Etiquette and Code of Ethics) Regulations, 1982. However, it is expected to be revised and updated by the newly formed Statutory body as Board of Ethics and Registration for Indian System of Medicine constituted under section 18 of the National Commission for Indian System of Medicine Act, 2020.¹³

Registration of AYUSH Medical Practitioners with State AYUSH Council¹⁴

2.1. Other Acts based on deployed manpower in AYUSH Hospital

- a. Indian Medical Council Act 1956¹⁵
- b. Indian Medical Degrees Act¹⁶
- c. Registration of Medical Practitioners with State Medical Councils
- d. Indian Nursing Council Act 1947¹⁷
- e. The Dentists Act 1948¹⁸
- f. The Physiotherapy Central Council Bill, 2017¹⁹
- g. Rehabilitation Council of India Act, 1992²⁰

3. Law governing storage/sale of drugs and safe medication: -

These laws control the usage of Ayurveda, Siddha, Unani & Homoeopathy medication, prevent their misuse, and regulate their sale.

These laws include:

- a. Drugs and Cosmetic Act 1940²¹
- b. The drugs control Act of 1950²²
- c. Central excise Act 1944²³(for a permit to use and store spirit including Asavarishtas)
- d. Narcotic Drugs and Psychotropic Substance (NDPS) Act, 1985²⁴ (like Ahiphena and Bhang)
- e. Retail drug license
- f. Sales of goods Act 1930²⁵
- g. Adulteration of drugs (IPC S. 274)
- h. Amendments made by Ministry of AYUSH from time to time.

4. Law governing the management of patients: -

These laws set standards and norms for the

conduct of medical skilled practice, prevention of unfair practices and management of emergencies.

These laws include:

- a. Drugs and Magic Remedies (objectionable) Advertisements Act 1954²⁶
- b. MTP Act 1997²⁷
- c. Birth and death and Marriage Registration Act 1886²⁸
- d. Indian Lunacy Act of 1912²⁹
- e. The Epidemic Disease Act of 1897³⁰
- f. Lepers Act³¹
- g. Guardians and Wards Act of 1890³²
- h. The Mental Health Act of 1987³³
- i. Indian Evidence Act³⁴ (disclosure of privileged/confidential patient related information before a court of law – under protest)
- j. Law of Torts³⁵
- k. Consumer Protection Act of 1986³⁶
- l. Protection of human rights Act³⁷

5. Law governing environmental protection: -

These laws are for the protection of the environment through the prevention of air, water, surface, and sound pollution.

These laws include:

- a. Biomedical medical waste management handling rules 1998³⁸ (Amended in 2000)
- b. Water (prevention and control of pollution) Act 1974³⁹

- c. The Noise Pollution (Regulation and Control) (Amendment) Rules, 2006⁴⁰
- d. Rules regarding the safe discharge of effluents in the public sewers/drains⁴¹
- e. The Air (Prevention and Control of Pollution) Rules, 1982⁴²
- f. Environment Protection Act of 1986⁴³

6. Laws governing the employment of manpower in Hospital: -

These embrace the employment of staff, their salaries and benefits.

These laws include:

- a. Child Labour Act⁴⁴
- b. Citizenship Act of 1955⁴⁵
- c. Employees provident fund and misc provision Act 1952⁴⁶
- d. Employment exchange (compulsory notification of vacancies) Act 1959⁴⁷
- e. Equal Remuneration Act of 1976⁴⁸
- f. Minimum Wages Act of 1948⁴⁹
- g. Payment of Bonus Act 1965⁵⁰
- h. Payment of Gratuity Act 1972⁵¹
- i. TDS Act⁵²
- j. Maternity Benefit (Amendment) Act, 2008⁵³
- k. Workmen's Compensation Act, 1923⁵⁴
- l. Persons with Disabilities Act 1995⁵⁵
- m. SC and ST Act of 1989⁵⁶
- n. Weekly Holidays Act, 1942⁵⁷

7. Regulations governing the business aspects of the hospital: -

These laws are applicable to hospitals in

reference to their business aspects.

These laws include:

- a. Charitable and Religious Trust Act of 1920⁵⁸
- b. Contract Act, 1972⁵⁹
- c. Customs Act of 1962⁶⁰
- d. Rules for the display of Red Cross Insignia⁶¹
- e. Vehicle registration certificate (Ambulance)

Other Important Periodical Reports and Returns to Health Authorities

- a. Cases of notifiable diseases as applicable in the state (Section 371, Delhi Municipal Corporation Act);
- b. Report of cases of food poisoning, if required by Municipal Health Authorities (Prevention of Food Adulteration Act, 1954);
- c. Incidence of needle stick injuries;
- d. Annual report under BM Waste Management Rules, 1998 (if applicable)
- e. Reports on the MTPs carried out;
- f. Reports on the USG abdomen (abdominal ultrasonography) done on the pregnant women.
- g. Reports on ADR (Pharmacovigilance)

Other Ethical mandates which the AYUSH hospitals or health care facilities have to maintain or follow to avoid legal implications:

a. Maintenance of patient medical records:

- i. All the AYUSH physicians should maintain medical records of the indoor patients for a period of 3 years
- ii. If required should be issued to the patients within 72 hrs.
- iii. Display of registration numbers:
- iv. Every prescription of physicians should display the registration number issued to them by the state council
- v. Use of Generic names of drugs: Physicians should always use the generic names in the prescriptions.

b. Utmost Quality Assurance in patient care:

The provision of minimal information about procedures, neglecting the sickest and time-consuming patients, the failure to provide necessary information, and the scheduling of insufficient time for patient visits should be avoided.

c. Exposure of Unethical Conduct: Bribery and corrupt practices should be avoided as it may potentially erode the trust and reputation of doctors, hospitals, and other medical practitioners.

d. Payment of Professional Services: The financial interest and fees for the services and operation should be discussed before rendering the services. No gain, no

payment, ideology should not be followed by the doctors.

CONCLUSION

With the changing times the legislations pertaining to medical establishments including AYUSH Hospitals have increased due to the health care needs of India. As of now there is no comprehensive healthcare act to bring all the legislations of the AYUSH healthcare sector together. Many of the medico-legal situations are realised in AYUSH sector when there is non-compliance of acts, rules and regulations. So, it has become inevitable for the AYUSH professional doctors to get acquainted with all related acts, rules and regulations and follow them honestly to ensure smooth functioning of their establishments and also keep abreast with the latest amendments to be on the safe side of LAW and provide quality care to the patients.

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