LEGAL ASPECTS IN HOSPITALS

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Format of Presentation

- Introduction & definitions
- Legal landscape in India
- Why is this important?
- Applicable Acts- an overview
- Salient features- some acts
 CPA,IDA,CLA, RTI etc
- Some practical aspects
- Conclusion



Introduction

- Hospitals are complex organizations, and governed by a plethora of legislations.
- Fundamental rights and Health are inextricably intertwined, esp Article 21- Protection of life & personal liberty
- The Directive Principles of State Policy (Art 37,38,39 & 47) cast an "obligation" upon the Govt to "take care" of health of the population.
- "Health" being a state subject, various states have passed laws for hospitals/establishments /nursing homes
- Knowledge of salient acts, rules & regulations is now absolutely essential for management of hospitals.

Definitions

- Legislation (Law): is a system of rules usually enforced through a set of institutions. <u>Law affects everyday life and</u> <u>society in a variety of ways.</u>
 - Statutory: refers to laws which are passed by legislature(Central/State), ratified by Pres/Gov
 - Regulatory: refers to administrative laws which are passed by Govt/agency, and may have an element of penalty involved.

Legal landscape in India

- Constitutional, Criminal, Civil Laws, Jurisprudence, Judicial Authorities, Quasi-judicial mechanisms
- Archaic laws still prevail despite new laws being enacted
- Process of law making has also been questioned, w.r.t Parliamentary Committees, consensus building.
- Rising trends of medical malpractice cases- 5.2 mn cases
- Pendency in courts around 3 crores (PRSI document 2018) & vacancies in lower & High courts
- Need for Judicial and police reforms is felt acutely by intellectuals, perceived/actual interference in other's areas
- All hospital standards in India mandate absolute compliance with statutory issues

Why is this important??

- Without 'knowledge' of applicable laws, we are ill prepared to handle certain issues with legal connotations
- Decisions taken with the best of intentions may be rendered invalid if not conforming to "laws".
- A reversal of the decision through judicial process (Courts/Tribunals) shows management in "poor" light, and also erodes the credibility of management.
- The affected party/ies after getting judgement in his/her/their favour walks "tall", and sometimes may challenge the superiors/mgmt.
- It is important to enforce discipline within the organisation

Article 21 COI- Salient judgements

- Health: The right to life includes the right to health.[State of Punjab vs M S Chawla, AIR,1997, SC,1225]
- It encompasses Right to live with human dignity, [F C Mullin vs Administrator of UT Delhi, AIR 1981, SC,746]
- Emergency medical aid- [Paramanand Katara vs UOI, AIR 1989, SC, 2039.]
- Timely treatment in Govt hospitals- [Paschim banga Khet Mazdoor Sangha vs State of WB, AIR, 1996, SC, 2426; para 9, 15, 16.]
- Medical Confidentiality- If prospective spouse is HIV +ve, the other spouse has aright to seek info from hospital. [Dr.T Yepthomi vs Apollo Hosp, JT (1998), 7 SC 626.]

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Classification of laws in hospitals

- Laws governing functioning of hospital
- Educational qualifications, practice and conduct of professionals

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- Storage / sale of Drugs and safe medication
- Management of patients
- Laws governing medico legal aspects of care
- Safety issues within hospital premises
- Employment of manpower
- Environment safety related legislation

1) Laws-hospital functioning

- Ownership:
 - Societies Regn Act 1860/Companies Act '56/ Charitable & Religious Trust Act 1920
 - Public hospitals- Govt or concerned Act, rules & regIns
- Hospital building: NBC-2005 & 2017
 - Permit from Municipality/NAC
 - Fire Safety Act 1986 NOC
 - Electricity Act 1910 & Rules-1956
 - Lift License (Lift & Escalators Act-state/UT)
 - Respective Hosp/NH/Estt Registration Act in state(s)
- Motor Vehicle Act 1939 & Rules

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Salient State legislations

- The Bombay Nursing Homes Regn Act, 1949
- The WB Clinical Establishments Act'50
- The MP Upcharya Griha Tatha Rujopchar Sambandhi sthapnaye adhiniyam,1973
- The Orissa Clinical establishments (control & regulation) Act 1990
- The Punjab State nursing home regn Act, 1991
- The Manipur homes and clinics regn Act, 1992
- The Nagaland healthcare estbs Act, 1997
- The AP private medical care Estb Act, 2002
- The Mizoram Clinical & Health Estb (regulation) Act 2007

2) Educational qual, practice & conduct

- Indian Medical Council Act 1956 & Rules'61
- IMC(Professional conduct, Etiquette & Ethics) reglns 2002, 2009, 2023(on hold!)
- National Medical Commission Act-2019
- Indian Nursing Council Act 1947 & Rules
- The Dentists Act 1948 & Regulations 1976
- Indian Pharmacy Act 1948
- Paramedical Council of India estd- 2005

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3) Safety, storage, & sale of drugs

- Drugs & Cosmetic Act '40, '82, '99 (BTS) & rules 1945
- Drugs Control Act 1950, & Rules 1960
- Narcotic Drugs & Psychotropic Subs Act'85
- Central Excise Act 1944
- Pharmacy Act 1948
- Sale of drugs:
 - Retail drug license/CST act/VAT act/ IPC sections
 - GST Act 2017- replaced earlier tax regime

Other rules, regulations,& guidelines for public organisations

- General Financial Rules 2005 & 2017:
 - Chapter 6: Procurement of Goods and services (GEM)
 - Rule 137: Fundamental principles of public buying
 - Rule 141: Rate contract
 - Rule 142: Registration of Suppliers
 - Rule 149-50: Purchase of goods through bids; tendering system
 - Rule 160: Transparency, competition, fairness and elimination of arbitrariness in procurement process
 - Rule 161: Efficiency, economy and accountability in public procurement system
 - Rule 163-177: Procurement of services
 - Rules 178-185: Outsourcing of services
 - Chapter 8: Contract Management
 - Rule 203-5: General principles and management of contracts

4) Management of patients

- Births, Deaths & Marriage registration Act'69
- The Epidemic Diseases Act 1897
- Indian Contract Act (Section 13)
- Mental Health Act'87, <u>amended in 2017</u>
- MTP Act 1971 *amended in 2021*
- Transplantation of Human Organs Act 1994, amended in 2011 and Rules in 2014
- PNDT Act'94 & Rules'96, amended 2011, 2012

Mental Health care Act 2017

Do You Know? In the Mental Healthcare Act, 2017:

- Rights given to persons with mental illnesses:
 - 1. Access and availability of mental healthcare at par with regular healthcare at Government facilities [Section18(1)]
 - 2. No cruel, inhuman and degrading treatment [Section 20]
 - 3. To be treated equal to persons with physical illness while providing healthcare
 - 4. Free legal aid to exercise their rights [Section 27]
- A citizen can make a written Advance Directive to decide:
 - 1. Care and treatment to/not to be given for mental illness
 - 2. Nominated Representative to make mental healthcare and treatment decisions on his behalf
- Person attempting suicide not to be punished under Indian Penal Code, presumed to be under stress and provided care, treatment and rehabilitation to reduce risk of recurrence. [Section 115]
- Child less than three years not to be separated from his mentally ill mother.
- Poor people to get free treatment for mental illnesses. [Section 18(7)]
- Free medicines for mental illness will be provided to all patients at all Government facilities. [Section 18(10)]





MTP Act 2021 amendments

- Ambit of Act also covers "unmarried" women
- Gestational age limit of fetus has been increased from 20 weeks to 24 weeks (for rape/incest victims) and beyond 24 weeks for 'substantial' fetal abnormalities.
- RMP opinion is needed from one upto 20 weeks, two RMPs (20-24 weeks); and State level medical Board for beyond 24 weeks.
- Breach of woman's confidentiality will attract fine and/or imprisonment upto 1 year.
- MTP can be performed only by specialists

PCPNDT Act-1994/2012 - overview



- Registration u/s 18 & renewal every 5 years
- Written consent from pregnant woman & non disclosure of sex of fetus u/s 5
- Maintaining records
 Form 5 & submission
 u/s 29
- Creating awareness through signages

Pressure Points..

- Form F
- Minor, unintentional errors should not lead to imprisonment
- Responsibility of any wrong form-filling should be borne by both patient and doctor
- Decoy operations (with malafide intention)
- Inadequate technical knowledge of App Auth
- Clear understanding needs to be developed



5) Medico legal aspects

- Indian Evidence Act 1872
- Law of privileged communication
- Consumer Protection Act 1986, 2019 and Rules 2020 (e-commerce)
- Certain sections of IPC 1860
 - 52,80,88,89,90,92,93,269
- Arbitration & Conciliation Act 1996
- Information Technology Act 2000
- Right to Information Act 2005, 2019

Salient Features of the CPA

- Presented in Parliament on 19th Dec 1986
- Passed in Parliament on 24th Dec 1986
- Promulgated on April 15th 1987
- Amended in 1993, 2002 2019, 2020 (e-com)
- Bare act (1986) has 4 chapters, 31 sections



Should media decide medical negligence cases??



Medical Negligence in media!!



GOVT SEEKS DETAILS

PARENTS' ALLEGATION: Fortis overcharged, kept them in dark over child's deteriorating condition and billed them for 660 syringes, 1,600 gloves. Final bill came to over ₹15 lakh even as girl could not be saved

HOSPITAL'S CLAIM: Child was admitted in very serious condition; they kept parents informed about all tests, investigation and treatment

GOVT: Union health minister J P Nadda has asked for details and **assured family of action**

What is negligence??

- It denotes a "careless state of mind" or "recklessness" on the part of a person
- Defn: Breach of a legal duty to take care which results in damage.... must prove the following:
 - That there was a legal duty to take care
 - That this duty was breached
 - This breach caused the damage[Percy & Charlesworth]
- Unexpected developments, complications and risks inherent in medical care do not imply negligence, if these have been explained to pt.

What is medical negligence?

- Defn: means a failure on the part of the doctor by not acting in accordance with medical standards in vogue, which are being practiced by a "prudent" doctor practicing in the same profession. [Modi's textbook on FMT]
- "Negligence means more than heedless or careless conduct, whether in omission or commission, it properly connotes the complex concept of duty, breach and damage thereby suffered by the person to whom the duty was owing."[Lord Wright, 1934]

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The journey from "Bolam"...

- Bolam vs Friern Hosp Mgmt Committee 1957
- Pt Rx for severe depression, ECT given
- Case filed for non admn of muscle relaxant/ manual restraint/ no warning of risks
- J Mc Nair ruled not negligent if actions are "in accordance with a practice accepted as proper by responsible body of medical professionals, even though other doctors adopt a different practice"
- However, it is the duty of the Dr to inform of risks involved in he treatment.

Bolitho....the journey continues..

- Bolitho Vs City & Hackney health Authority '97
- Minor claimant sued City Hospital for severe brain damage due to failure to intubate...
- Court examined expert witnesses from both sides... agreed with defendant witnesses
- Agreement was based on "logical analysis" of the case scenario by Lord Browne Wilkinson
- "Doctrinal shift" giving more power to Judiciary to negate "illogical" expert witnesses

Montgomery vs Lanarkshire Health Board, UK Supreme Court 2015

- Nadine Montgomery was pregnant with 1st child
- She had Type I DM was concerned about size of her baby, enquired during ANC visits.
- Risk of "shoulder dystocia" was not discussed, and plan was made for normal delivery.
- During delivery it occurred and 12 min delay caused cerebral palsy due to hypoxia
- Lord Neuberger & Lady Hale with 5 other judges decided "that doctor should have provided all info, and allowed her to take decision regarding modality..."

Current Status of cases in India('22)

Location	Cases filed	Cases disposed	Pending	% disposal
NCDRC	138676	116508	22168	84.01%
SCDRCs	874562	755863	118699	86.4%
Distt Forum	4472029	4057971	414058	90.7%

COPRA-2019 a primer



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Some genuine concerns....

- Society & Medical Professionals...
- Rule of law or rule of rulers...
- The menace of corruption....
- Demand supply gaps & inequitable distribution
- Social media use and effects...
- Delay in judicial processes, and backlog of cases
- Urgent need for reforms & transparency

Which one would you choose??





RTI Act 2005 - Introduction...



 Several states TN, Goa, Karnataka, Rajasthan, Delhi, Maharashtra, MP, J & K etc had passed RTI before 2005

 Maharashtra state's act was the "template" on which RTI Act was passed in June 2005.

What is right to information??



Definitions...

- Information: Any material in any form incl records, documents, memos, e-mails, opinions, advices, press releases, circulars, orders, logbooks, contracts, reports, papers, samples, models, data material in any electronic form..
- Public authority: any authority/body/institution of self govt estd/constituted by or under Constitution, laws by Parliament, or State legislature, or by Govt notification, if owned, controlled or substantially financed,(incl NGOs) directly or indirectly by funds provided by Govt

Process flow chart for RTIs



Salient judgements (CIC)

- ■MK vs Dept of Revenue: Annual Prop return is 'personal'.[02/IC(A)/CIC/'06; 22.6.06]
- AV vs Dt Gen I Tax & BHV vs Canara Bank: PAN need not be disclosed.
 [05/OC(A)/CIC/' 06 dt 3.3.06]
- MR vs JIPMER dt 14-06-2007: DPC minutes and the connected proceedings are not exempt from disclosure. How-ever, ACRs considered for DPC are exempt.[CIC Digest (Vol-II, 1557(337)]
Salient judgements.. CIC

- ■VRS vs MoD: **Untraceability** of information is accepted in case PIO made diligent search to trace. [CIC/AT/A/2006/00073, dt 4.7.06]
- RA vs Dept of Posts & MKN vs Dept of Info Tech: Applicant has asked for huge amount of info in a pre-designed format. Info available in the office is not in this format. [CIC Digest (Vol-II)2466(1969) dt 4-9-08 & 1523(291) dt 4-6-07]
 NA vs MOHFW, 34/ICPB/'06 dt 19.06.06: CIC has no power to enquire into why, how and in what manner a decision was taken

Salient judgements CIC...

- SKNA vs CVC 92/IC(A)/' 06 dt 7.7.06: Information relating to investigation that have been completed to be disclosed. If investigation is in progress, disclosure is exempt U/S 8(1)h.
- RKG vs IT Appellate authority, CIC/AT/A /2006/ 00185 dt 18-9-06: Interpretation of a given law/rules/regulation is not information under RTI & CPIO is not reqd to give the same. This info is available in public domain.

High Court judgement on RTI

- Dr C Pinto vs Goa State Info Com in WP no 419/2007 at HC of Mumbai at Goa:
 - Term info does not include answers to questions like "why"- which would be the same thing as asking the reason/justification for a particular thing.
 - □Justifications are matter within domain of adjudicating authorities & cannot possibly be classified as information.
 - Circulated vide memo no 1/7/2009-IR dt 1st June 2009 by Min of Personnel, Public Grievance & Pension, DOPT, GOI.

RTI Act amendment 2019

- The proposed changes to the tenure, salaries and service conditions of Chief Information Commissioners has resulted in opposition walking out of both LS and RS
- Almost all former CICs and activists are in favour of not amending the RTI act as it strengthens democracy by increasing "transparency" in decision making.
- Hon'ble SC has re-affirmed it's faith in ensuring transparency in the Electoral Bonds case recently.

6) Safety issues in hosp premises

- Boilers Act 1923
- Indian Explosives Act 1884 & Rules
- Gas cylinder Rules 2004
- Atomic Energy Act 1962, Rules and Safety Codes- AERB, BARC, Medical Physics dept
- Prevention of Food adulteration Act & Rules
- Manufacture, storage & import of hazardous chemical rules 1989
- Prevention of Violence against Medicare persons and Medicare Institutions Act (25 states)
- Prevention of Sexual Harassment of women at workplace (POSH) Act-2013

Need for a separate law

- Sexual harassment is endemic, often hidden, and present in all kinds of organizations.
- Realization that sexual harassment cannot be accepted.
- Supreme Court recognizing the need for a law in this regard laid down guidelines for prevention and punishment of sexual harassment in work place in Vishaka v. State of Rajasthan (1997) 6 SCC 241.
- This case revealed the hazards that a working woman is exposed to.
- Supreme Court recognized sexual harassment as human rights violation and gender based systematic discrimination that affects women's Right to Life and Livelihood and that right to life means life with dignity.
- Case of Rupan Deol Bajaj and Anr. v. KPS Gill (1995) 6 SCC 194 can be seen to understand the subtlety of the concept.

POSH Act-2013

WHAT IS THE POSH ACT 2013?



Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act was passed in 2013



PoSH Act includes unwelcome remarks and actions



Physical advances, sexual favours demand, lewd jokes also unlawful



Complaints to be filed within 3 months of incident



Internal Complaints Committee handles PoSH cases



Inquiry has to be completed within 90 days



Listed companies have to disclose number of cases filed every year



7) Employment of Staff

- Workmen's Compensation Act 1923
- Payment of Wages Act 1936
- Industrial Disputes Act 1947
- Minimum wages Act 1948 & rules
- ESI Act 1948 & Central Rules 1950
- EPF & Misc provisions Act 1952

Objectives of ID Act 1947

- Promotion of measures for securing & preserving amity & good relationship
- Mech for investigation & settlement of ID between Employer & employee; employee
 & employee; with right to representation by recognized & registerd TUs
- Prevention of illegal strikes & lockouts
- Relief to workers in lay offs/retrenchmt
- Collective bargaining & negotiations

Is hospital an industry??

- Earlier in 1960, State of Bombay vs Hospital Mazdoor Sabha(HMS) in Bombay HC, hospitals were covered under "industry" as defined in the Act.
- In 1970, Management of Safdarjung Hospital vs Kuldip Singh Sethi, the HC held that SJH is not an industry by using "analogous activity test"
- Later a "triple test" was laid down by SC ('78) acc to which in an industry there should be systematic activity, co-operation between Employer and employee for production and distribution of products/services

Industries covered..

- Industry- any business, undertaking, trade, manufacture or calling of employers; which incl handicrafts, services, vocations etc
- Workmen: any person employed in any industry to do any manual, tech, supervisory, clerical work for hire or reward.
- SC('78)-BWSSB vs Rajappa; held that applies to establishments run without profit motive, undertakings on NPNL, ie municipalities, research instt, service assocn, shops, clubs, banks, educational institutions.

Industrial Disputes covered..

Individual disputes

- Wrongful dismissal
- Propriety/legality of orders passed
- Inadequate compens
- Re-instatement
- Supreme Court: dispute between E & e, not ID, unless matter is taken up by other workers/TU

- Collective disputes:
 - Payment of wages, period, mode.
 - Hours of work & rest
 - Allowances, leaves
 - Bonus, PF,Gratuity
 - Classification of workers, grading
 - Disciplinary rules, standing orders
 - Retrenchment of workers

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Machinery for settling disputes

- Works Committee- thru collective bargaining & negotiations
- Conciliation Officers- single person chairs
- Board of Conciliation-Chairman, 2-4 members
- Courts of Inquiry: Labour Court, Ind T, Natl T
- ID can't be taken *directly* to Labour Court /Industrial Tribunal, except in specific cases
- If matter is not settled in conciliation, open to Govt to refer to LC/IT/NT, esp matters listed in Schedule II/III

STRIKES- a perspective

- Defn: "Cessation of work by a body of persons employed in an industry by acting in concert/combination"
- Three essential ingredients:
 - Plurality of workmen
 - Cessation/refusal to do work
 - Concerted/ combined effort
- Includes under its ambit all forms, methods like pen-down, partial etc

Conditions to be fulfilled(PUS)

Section 22:

- Notice in Form L before 6 weeks, repeat for new S
- Can't go on Strike within 14 days of giving notice
- Hence legal strike ONLY in last 4 weeks of notice period
- Can't strike if conciliation proceedings are pending before Con Officer
- Can take place after 7 days of conclusion of case

• Section 23:

- Prohibited if case is pending before an arbitrator
- In case proceedings before LC/IT/NTprohibited till 2 months after it is over
- Prohibited during period of settlement or when award is in operation

Illegal strikes

- Section 24 states:
 - Any strike contravening Sec 22 & 23.
 - Any strike contravening prohibitory orders by Govt u/s 10 & 11
- Implication of illegal strike:
 - Cannot claim wages for the duration of strike
 - Can also be punished under this act (1-6 months/Rs50-1000) & relevant disciplinary rules

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7) Employment of Staff...contd..

- The Maternity benefit Act, 1961
- The Payment of Minimum wages Act, 1961
- Payment of Bonus Act 1965
- The Contract labour (R & A) Act 1970
- Payment of Gratuity act 1972
- The Equal Remuneration Act 1976
- Persons with Disability Act 1995

Contract Labor Act- Introduction

- Outsourcing of 'non core' services in hospital is very common
- Private sector hospitals have outsourced more number of services
- GOI in favor of service 'outsourcing'
- Legal standing is the same in all cases



CLA: Indian Scenario

- Lot of confusion w r t Contract Labour in organisations (both public and private sectors)
- Sometimes conflicting provisions in different Acts are responsible, e.g Factories Act
- Executive wing is not aware of "nuts & bolts" of the various Acts, but is 'implementing' agency
- Fear of "license permit raj" still prevail
- Contract labourers continue to be discriminated against and usually get a "raw" deal.
- Note from CS to Secy Labour highlights some of these issues and resultant problems(2012).

CLA: Indian scenario....solutions!

- More awareness sessions are required for all parties i.e PEs Contractors, Supervisors etc
- Workshops to clarify legal loopholes with Lawyers dealing with Labour laws & Judges
- Better working conditions for Contract labour will ensure feeling of 'identification' with establishment
- Wherever 'regular' employees can be recruited, should not be opened up for contract labour, as it is perennial
- Participatory management works best, even with contract workers!

Other Labour laws applicable

- The Factories Act 1948- makes no discrimination between employees of Estb or Contract workers w.r.t all priveleges & benefits
- The EPF & Misc provisions Act : mandatory contributions of contract workers paid by PE
- The ESI Act 1948: entitled for the benefit if they meet the requirement, contributions paid by PE
- The Industrial Disputes Act- between Organization and employees & also between Contractor & Contract Labour
- The Workmen's Compensation Act 1923

8) Laws for environment safety

- Air (prev & control of pollution) Act '81, '87
- Water (prev & control of pollution) Act 1974
- Environment Protection Act 1986 & Noise pollution control Rules 2000, EPA rules 2003
- BMW (Mgmt & handling) Rules 1998, 2006, 2009
 & 2016
- E-waste management Rules 2016
- Solid waste management Rules 2017
- Respective municipality bye laws
- Certain provisions of IPC- 268 & 279

Medical records: Ownership, Confidentiality

- MRs are considered as property of the hospital, kept primarily for the patient
- The personal and medical data is confidential communication, and hence is property of patient
- Hence, **CANNOT** be released without consent of patient
- Patients right to privacy must be ensured
- MRO should ensure that no unauthorized persons enter MR deptt
- MRs should be kept securely in wards, and sent to MRD only through hospital staff
- MRs should be stored in a secure area

Release of Information to patients

- As per current legal status patients have full rights over the medical records
- Any request should be complied with within 72 hours, after establishing identity of patient/ next of kin
- Hospital's policy will determine the 'method' of release of information.
- In MLC/ Medical Board cases this right is suspended
- Under RTI Act, information should be disclosed within time frame of 48 hrs OR 30 days as specified in RTI application.
- Ordinarily, the discharge summary and all investigation reports are provided to patients.

Release of Information to relatives

- Not to be given, unless patient is dead
- In case of children, consent of parents/legal guardian
- Request to be taken in writing with full details, and relationship (usu next of kin)
- Establish proof of relationship through documents
- Obtain third party clearance in cases where information is sought under RTI
- Obtain written receipt of records provided

MR Policy development; some questions to be answered

- Does the consent form have provision for ROI
- Is anyone from outside hospital allowed access
- What provisions are there for law enforcing agencies?
- Rules for securing MRD after office hours?
- Release of information for research and publications?

- Any rules for family members, friends, insurance companies, lawyers asking information?
- Any separate rules for minors?
- What about patients who have died?
- Penalties for breaking these rules?

Some Practical aspects



- Develop good/cordial relations with Judiciary at all times
- Appoint a trustworthy Faculty member as Officer I/C for all statutory issues
- Understand the distinction between Civil & criminal cases
- Regular sensitization sessions for concerned staff & Officers
- Have a dashboard of "red flags" for issues where "occupier" is involved
- Take professional counsel as soon as possible

Conclusion



- Ignorance of the law,
 does not constitute an excuse.
- No man is above the law and no man is below it; ...
 Obedience to the law is demanded as a right; not asked as a favour.
 - Theodore Roosevelt
- Awareness programs are essential

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