

LEGAL ASPECTS IN HOSPITALS

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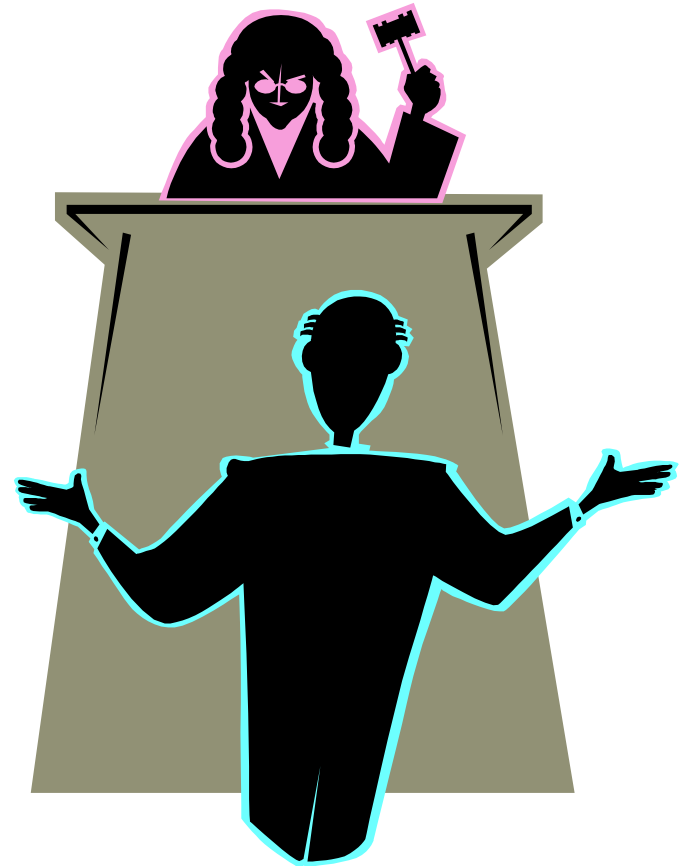
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Format of Presentation

- Introduction & definitions
- Legal landscape in India
- Why is this important?
- Applicable Acts- an overview
- New Criminal Laws-2024
- 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. *Law affects everyday life and society in a variety of ways.*
 - **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

Classification of laws in hospitals

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

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

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**

4) Management of patients

- Births, Deaths & Marriage registration Act'69
- The Epidemic Diseases Act 1897
- **Indian Contract Act (Section 13)**
- Mental Health Act'87, amended in 2017
- 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 [Section 18(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)]**



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NATIONAL MENTAL HEALTH PROGRAMME

Ministry of Health & Family Welfare, Government of India, Nirman Bhawan, New Delhi - 110108
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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-(repealed)
- Law of privileged communication
- **Consumer Protection Act 1986, 2019 and Rules 2020 (e-commerce)**
- Certain sections of IPC 1860- (repealed)
 - 52,80,88,89,90,92,93,269
- Arbitration & Conciliation Act 1996
- Information Technology Act 2000
- **Right to Information Act 2005, 2019**

Our new Criminal Laws-2024



- Passed in last session of 17th Lok Sabha *sans* debate
- GoI claims- new laws signify end of “colonial” era
- Old wine in new bottle states Opposition
- Implemented w.e.f 1st July 2024

Pros & Cons of new Criminal laws

- Zero FIR- irrespective of location of crime
- Online reporting allowed
- Electronic summons
- Copy of FIR to be provided to victim
- Mandatory crime scene videography
- Forensic investigation needed in cases with 7 yr RI
- Police custody for 15 days, can be more.
- Detention of UT if more than 1 offence increased
- Power to handcuff for economic offences
- Solitary confinement
- Fundamental rights suppressed
- Sec 106 BNS replaces Sec 304A of IPC- more trouble for Medicos?

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]*

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 the 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

CONSUMER PROTECTION ACT 1986	PROVISIONS	CONSUMER PROTECTION ACT 2019
No separate regulator	Regulator	Central Consumer Protection Authority (CCPA) to be formed
Complaint could be filed in a consumer court where the seller's (defendant) office is located	Consumer court	Complaint can be filed in a consumer court where the complainant resides or works
No provision. Consumer could approach a civil court but not consumer court	Product liability	Consumer can seek compensation for harm caused by a product or service
District: up to ₹20 lakh State: ₹20 lakh to ₹1 cr National: above ₹1 cr	Pecuniary jurisdiction	District: up to ₹1 cr State: ₹1 cr to ₹10 cr National: Above ₹10 cr
No provision	E-commerce	All rules of direct selling extended to e-commerce
No legal provision	Mediation cells	<small>BCCL</small> Court can refer settlement through mediation

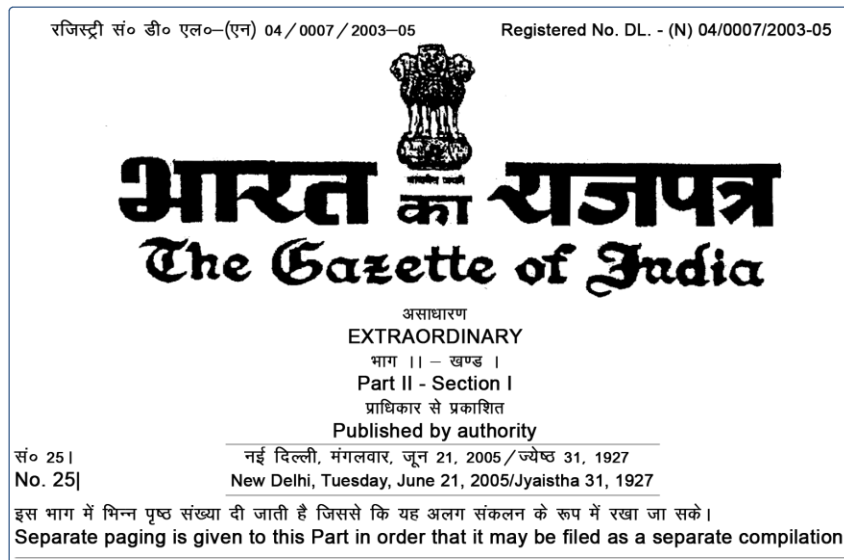
Some genuine concerns....

- 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??

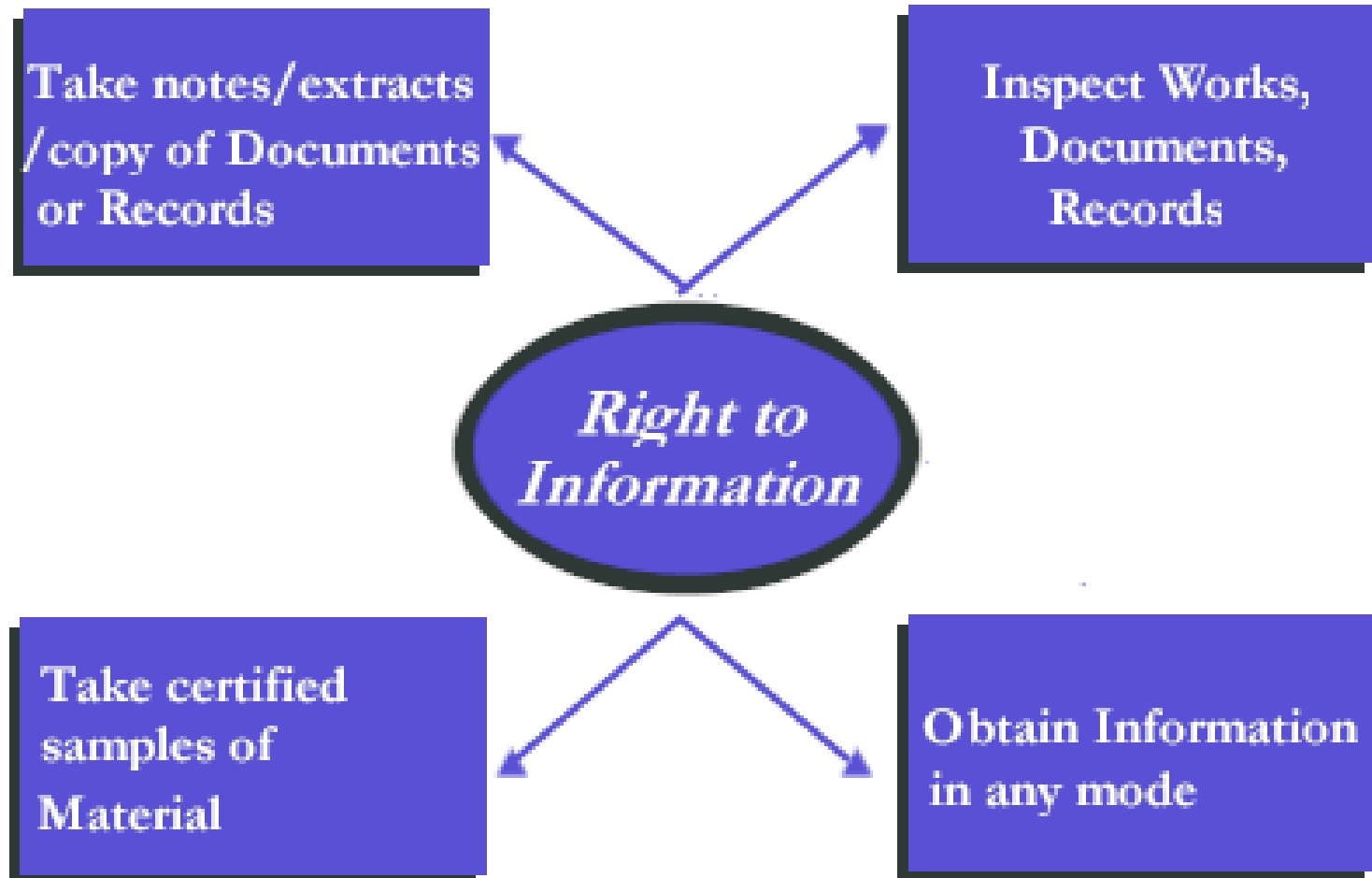


RTI Act 2005 - Introduction...

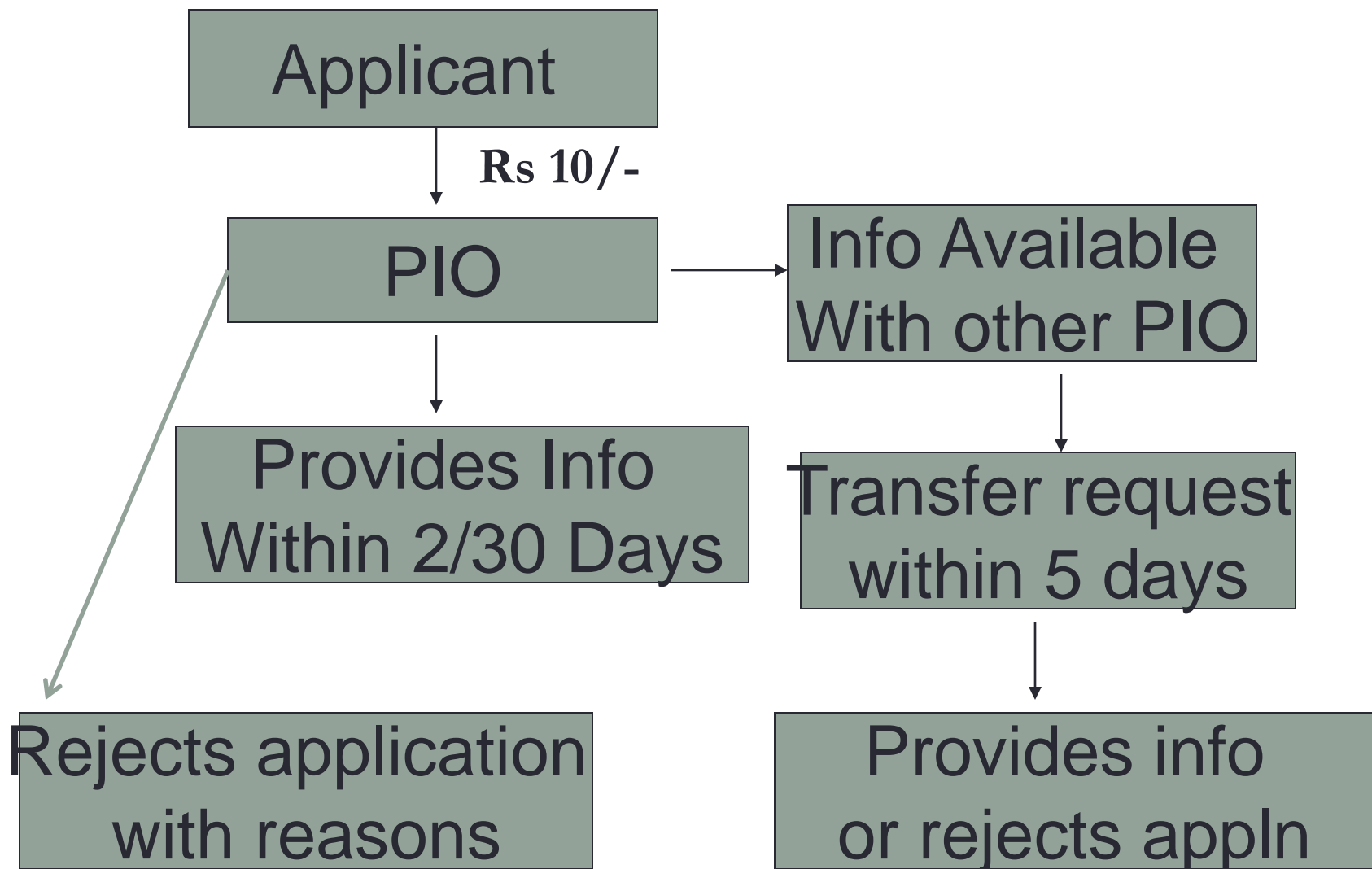


- Several states TN, Goa, Karnataka, Rajasthan, Delhi, Maharashtra, MP, J & K etc had passed RTI before 2005
- Maharashtra state's act was the "template" on which RTI Act was passed in June 2005.

What is right to information??



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

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 & registered TUs
- Prevention of illegal strikes & lockouts
- Relief to workers in lay offs/retrenchment
- Collective bargaining & negotiations

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

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/NT- prohibited 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

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

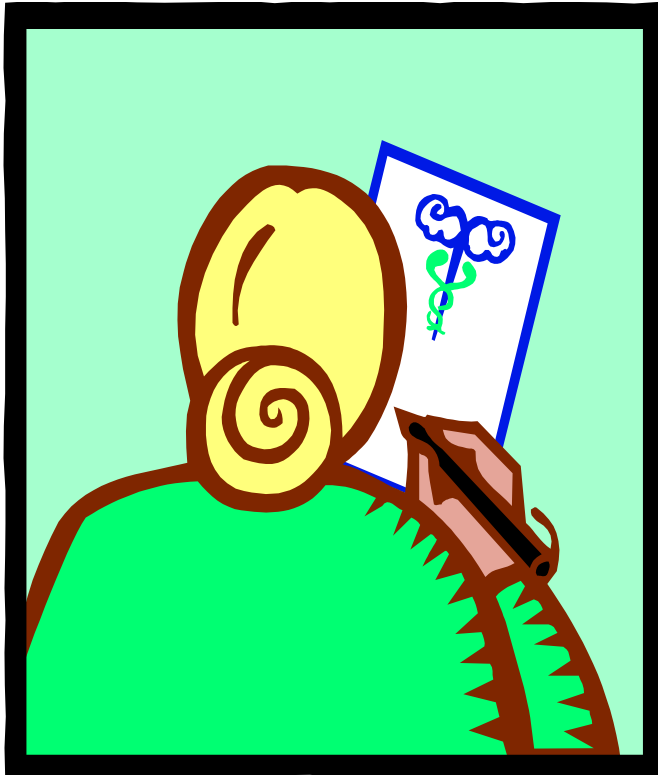
- Not to be given, unless patient is dead
- In case of children, consent of parents/legal guardian
- Request to be taken in writing with full details, and relationship (usu next of kin)
- Establish proof of relationship through documents
- Obtain third party clearance in cases where information is sought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

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

