

Cost of setting up Clinical Establishments (CEs)

Shubho Roy

November 28, 2018

Overview

- Introduction to Clinical Establishment law
- A case for Cost-Benefit Exercise
- The UK example
- How would the law fare in India?
- Methodology
- Findings

Part I

Clinical Establishments (Registration and Regulation) Act

Need for the law

Background

- Health care services in India reported to have:
 - Inadequate and inappropriate treatments
 - Excessive use of higher technologies
 - Wasting of scarce resources
 - Medical malpractice and negligence
- Need to monitor services offered in public and private facilities
- *Clinical Establishments (Registration and Regulation) Act* introduced to deal with these problem

The Clinical Establishment Act

What does it do?

Law	<i>Clinical Establishments (Registration and Regulation) Act, 2010</i>
Objective	Register and regulate “clinical establishments” <i>“A hospital, maternity home, nursing home, dispensary, clinic, sanatorium or an institution by whatever name called that offers services, facilities requiring diagnosis...”</i>
Regulator	National Council, State Council and District Registering Authority

How does it work

Registering Clinical establishments

Minimum requirement

- Minimum standards of facilities and services
- Minimum requirement of personnel
- Compliance with standard treatment guidelines
- Details of rates charged and facilities available
- Provisions for recording and reporting

Validity

Five years

Part II

A case for Cost-Benefit Analysis

Pitfalls in the regulation-making process

- Individuals thinking about regulation: *difference between using reason and appearing to use reason*
 - Most humans are intuitive: they form an opinion and then use reasoning for social purposes (Mercier and Sperber, 2011)
 - Behavioral/cognitive biases: confirmation bias, availability heuristic; optimism bias
 - High bar for evidence that goes against our views, but happy to accept weak supportive evidence (Ditto, Pizarro and Tannenbaum, 2009)
 - Power and complexity make good reasoning less likely to happen

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 - Power and complexity make good reasoning less likely to happen
- Organisations making regulation
 - The "work" of regulation cannot be easily observed - limits of internal accountability
 - Risk of group-think in teams
 - Hierarchy may limit participation

Pitfalls in the regulation-making process

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 - Comprehensive: society-wide impacts are included
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- Potential of CBA
 - Induces optimisation: alternatives are compared
 - Comprehensive: society-wide impacts are included
 - Precise: costs and benefits are quantified/monetised
- The biggest potential contribution: the process of analyzing, questioning, understanding real-world impacts and exploring assumptions
- CBA can help make the consultation process more productive

The Concept of Cost Benefit Analysis

- **Regulatory Impact Analysis (RIA):** a **structured process** that can help the regulator in taking decisions by:
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The Concept of Cost Benefit Analysis

1. Define the objective and describe the need for regulatory action
2. Define the Baseline and set the Time Horizon of Analysis
3. Identify a Range of Regulatory Alternatives
4. Identify the Consequences of Regulatory Alternatives
5. Quantify and Monetize the Benefits and Costs
6. Discount Future Benefits and Costs
7. Scenario analysis
8. Present the findings

Part III

The UK example

Language test

Cost:

1. 15% doctors required
2. GBP 132 per test

Benefits:

1. Prevent:
1 death, 2 cases of severe harm and 15 cases of moderate harm...
2. Cost of GBP 0.77 million vs benefits of GBP 2.01 million

Part IV

How would the Clinical Establishment law fare?

Costing exercise

- We did not perform a cost-benefit analysis
- We want to see effect on a clinic that meets standards
- On the question of **cost**

How did we do it?

- We went through *Clinical Establishment Act Standard for Clinic / Polyclinic (Only Consultation)* to identify requirements

Minimum standards

Clinic (Only Consultation)

Definition

"A clinical establishment providing examination, consultation, prescription to outpatients including dispensing of medicines by a single/general practitioner/specialist doctor/super-specialist doctor"

Legal requirements

- Registration of medical doctor with central/state medical council
- Biomedical management handling rules, 1998
- Provisional registration of the clinic

Infrastructure requirement

- Common area - 35 sq ft carpet area
- Consultation room - 70 sq ft carpet area

Minimum standards

Clinic (Only Consultation)

Furniture/fixtures

- Table
- Chairs
- Examination table
- Screens
- Foot step
- Stools
- Storage cabinet for records
- BMW storage area

Equipment/instrument

- Stethoscope
- Thermometer
- Sphygmomanometer (B.P. Apparatus)
- Weighing machine
- Resuscitation Equipment
- Ambu Bag
- Oxygen Concentrator
- Fire Extinguisher

Penalties

Offence	Penalties in rupees		
	<i>First offence</i>	<i>Second offence</i>	<i>Subsequent offence</i>
Running CE without registration	50000	200000	500000
Violation of any other provision of the act	10000	50000	500000
Serving in unregistered CE knowingly	25000		
Minor deficiencies which do not pose imminent danger	10000		

Table 6: Penalties under *Clinical Establishments (Registration and Regulation) Act*

Unclear areas

1. What constitutes Resuscitation Equipment (Annexure 4, S. No. 1)
 - List of Resuscitation Equipment from *Clinical Establishment Act Standard for Hospital (Level 1)*
2. Consumption rate of Emergency Drugs (Annexure 5, S. No. 1 – 14)
 - List of emergency and non emergency drugs from *Indian Public Health Standards: Guidelines for Community Health Centres*
 - Rate suggested by medical practitioner
 - Low consumption drugs @ 5/month
 - High consumption drugs @ 1/day

Part V

Methodology

Sources for costing

- Furniture: Amazon and Industry Buying
- Equipments: Amazon and Industry Buying
- Rent: Magic Bricks
- Salaries: Naukri.com
- Drugs: Med India, Med Plus Mart and India Mart

Assumptions

Location of the clinic	Saket, New Delhi
No. of days clinic will be open in a month	26
No. of patients visiting	15 (Pessimistic) 30 (Realistic) 45 (Optimistic)
Quantity of low consumption drugs per month	5
Quantity of high consumption drugs per month	26

Part VI

Findings

Expenditure

Expenditure	Year 1	Year 2
Capital Expenditure	₹94,114	₹27,324
Revenue Expenditure	₹3,66,940	₹3,66,940
Total Expenditure	₹4,61,054	₹3,94,264

Cost per patient

	Pessimistic 15 patients/day	Realistic 30 patients/day	Optimistic 45 patients/day
Year 1	₹99	₹49	₹33
Year 2	₹84	₹42	₹28

Thank You