

# Cost of compliance for clinical establishments

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 [blog.theleapjournal.org/2017/09/cost-of-compliance-for-clinical.html](http://blog.theleapjournal.org/2017/09/cost-of-compliance-for-clinical.html)

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The Clinical Establishments (Registration and Regulation) Act, 2010 (Clinical Establishments Act) is facing resistance from the medical fraternity. The Indian Medical Association claims that the law will cause an increase in the cost of treatment and adversely affect small and medium size clinical establishments such as a clinic run by one or a few doctors. The Health Minister for Delhi promised that the law, as drafted by the Planning Commission, will not be implemented in Delhi. On 27th April, 2017, doctors observed 'black day' to protest against the law.

## Costs and benefits in a sound regulatory process

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All regulation creates constraints for private persons. In general, the constrained cost minimisation of private persons will yield an inferior value (i.e. higher cost) when compared with the unconstrained cost minimisation. The question that society must ask is about the extent to which the regulation yields benefits that outweigh the costs.

In a sound regulatory process, this step is built into the regulatory process through administrative law. It is called *Regulatory Impact Analysis (RIA)* or *Cost Benefit Analysis (CBA)*. The formal process of undertaking RIA/CBA is a healthy one for three reasons:

1. The *process* of undertaking the CBA helps policy makers improve thinking about the problem that we seek to solve and the alternative mechanisms that could be adopted.
2. The citizenry obtains greater transparency when the CBA is released. Officials get an opportunity to display expertise in the release of the documents. Transparency and expertise create legitimacy.
3. The public, and all interested parties, are able to modify assumptions and rework the thought process of the regulator. This creates a more informed public debate.

As an example of doing cost-benefit analysis, consider the way the the British Government proposed a regulation requiring clinics to check the English language skills of doctors before he/she is appointed in a clinic. The cost-benefit analysis weighs the costs and benefits of various policy option including the option to do nothing. On the side of costs, the government estimated that 15% of the doctors will be required to take the test, which would cost GBP 132 per test. On the side of benefits, it was estimated that over a period of 10 years, English competence, would prevent:

| *1 death, 2 cases of severe harm and 15 cases of moderate harm...*

The quality adjusted life year was valued at GBP 60,000. The litigation costs arising out of the injuries from poor English knowledge of doctors was estimated to be half of that. These would be savings to society: clinics and patients. The analysis concluded that the costs would be around GBP 0.77 million while total benefits would be GBP 2.01 million (on a net present value basis). As the estimated benefits outweigh the cost, the proposed regulation is justified.

Turning to the Indian context, while the protesters are arguing about the increased costs of treatment under the proposed law, estimates about the financial implications for providers are lacking. Like the Clinical Establishments Act, the Right to Education (RTE) Act also focuses on the provision of inputs and not on outcomes. Most of the requirements under the RTE act impose costs on schools without any demonstration on improved learning outcomes. Wadhwa (2010) shows that learning outcomes are not correlated with the school infrastructure, which forms majority of the measures required under the RTE Act. Wadhwa's research shows that the most significant factor for learning outcomes is *teacher attendance*. Sadly, this is not part of the RTE Act measures. On the other hand there is research to show that complying with the RTE Act, substantially increases the cost of school fees. Centre for Civil Society calculated the compliance cost of RTE in Delhi. They found that due to RTE norms, the average cost per child will go up to INR 2,223 per month from the current fee of INR 322 per month, indicating an increase in average fee by 590%. While some the RTE Act requirements like the need for a 800 sq.m. playgrounds have been relaxed to 200 sq m most of the other input based requirements remain. Muralidharan and Sundararaman (2009) carried out a randomised control trial in five districts of Andhra Pradesh with 500 schools over two years. Teachers were offered a bonus for gain in standardised scores. The authors conclude that teacher performance pay led to significant improvements in student test scores. The results also showed positive spillovers i.e. students further more performed better in subjects for which teachers were not given incentives. However, such measures are yet to be incorporated into the RTE law.

In this article, we estimate the cost of setting up a basic doctor's clinic which complies with the standards under the Clinical Establishments Act.

## The standard

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The Clinical Establishments Act prescribes standards for health care facilities. It covers pharmacies, dispensaries, clinics, diagnostic centres, and hospitals of various types and sizes. Standards have been made for different types of clinical establishments. The most basic type of clinical establishment under the Act is: *Clinics (only consultation)*. This type covers a simple doctor's clinic. A doctor's clinic is usually the first, and most frequent, point of contact between doctors and patients. While these locations are limited to an interaction with a doctor, a few minor procedures like dressing, administering injections, etc. may be provided. No overnight stay or observation can be carried out in these clinics. The standards for this type of clinic constitute the smallest possible compliance

cost under the law. We studied this standards document, *Clinical Establishments Act Standard for Clinic/Polyclinic only Consultation*, in order to estimate the cost of compliance.

## Methodology

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1. We identified the requirements from the standards document.
2. Made certain assumptions, like location of clinic, consumption of medicines, registration costs, etc.
3. Obtained prices of the items required.
4. Estimated the annual compliance cost.
5. Drew up three scenarios based on assumptions about number of patients visiting each day.
6. Estimated the compliance cost per patient.

### *Identifying requirements:*

The standards document groups the requirements into seven categories:

1. **Infrastructure:** Lays down the minimum floor area for the clinic.
2. **Furniture/fixtures:** Mandates that the clinic have cupboards, tables, observation tables, etc.
3. **Human resource:** Requires that the clinic have at least one support staff person.
4. **Equipment/instruments:** Lists out the medical equipment that a clinic should have.
5. **Medicines:** Requires the clinic to maintain inventor of 13 essential medicines.
6. **Legal/statutory requirements:** Requires the doctor to be registered with the state medical council, the clinic be registered under the Clinical Establishments Act, and comply with environmental laws for disposing biomedical waste.
7. **Record Keeping:** The clinic must keep records of all patients for 3 or 5 years.

### *Assumptions:*

We made the following assumptions:

- **Location:** The clinic is located in Saket, New Delhi.
- **Number of working days:** The clinic is open for 26 days in a month.
- **Resuscitation equipment:** The phrase *resuscitation equipment* in the standard is ambiguous. We assume that the requirements for hospitals would also apply to clinics.
  
- **Classifying medicines:** We divided the list of medicines into *emergency* and *non-emergency* using Indian Public Health Standards: Guidelines for Community Health Centres.
- **Consumption rate of medicines:** We assume that emergency medicines are consumed at the rate of 5 per month and non-emergency medicines, at the rate of 26 per month. These values were chosen through discussions with doctors.

- **Registration cost:** The registration cost under the Clinical Establishments Act is assumed to be Rs.1000, which is generally the case.

*Sources of price data:* We found furniture and equipment prices from [Amazon.in](https://www.amazon.in) and [Industrybuying.com](https://www.industrybuying.com). Rental charges were estimated using [Magicbricks.com](https://www.magicbricks.com). The salary of the helper was estimated using [Naukri.com](https://www.naukri.com). Prices of medicines were obtained from [Medindia](https://www.medindia.com), [MedPlus Mart](https://www.medplusmart.com) and [Indiamart](https://www.indiamart.com).

*Exclusions:* Our estimates are conservative in that the following are not counted:

- Doctor's profit/income
- Cost of keeping medical records
- Water charges
- Cost of board/signage
- Compliance cost under [bio-medical waste management laws](#)

*Number of users.* The compliance costs will be distributed amongst the patients visiting the clinic. This requires assumptions about traffic at the clinic expressed in patients per day. We considered three scenarios: Optimistic (45/day), Realistic (30/day) and Pessimistic (15/day).

## Findings

The calculations were made [using a spreadsheet that is released to the public](#).

Table 1 reports the total cost for setting up and running the clinic for two years, and the costs per patient based on our scenarios. In Table 2, we broke the cost down into sub-components to see which part accounts for the largest share.

<b>Expenditure/Scenarios</b>	<b>Year One</b>	<b>Year Two</b>
<b><i>Compliance cost:</i></b>		
Capital Expenditure	95,114	27,324
Revenue Expenditure	4,29,640	4,29,640
<b>Total Expenditure</b> (Sum of capital and revenue)	<b>5,24,754</b>	<b>4,56,964</b>
<b><i>Cost per patient:</i></b>		

Pessimistic (15 patients/day)	112	98
Realistic (30 patients/day)	56	49
Optimistic (45 patients/day)	37	33

*Values are in Rs.*

Table 1: Compliance cost and cost per patient

This suggests that the standard may impose a cost of around Rs.50 per patient, under the 'Realistic' case. These are significant values when compared with the typical charges at clinics in Delhi.

Head	Year One	Year Two
Infrastructure	39.5	45.4
Furniture	6.2	0.6
Human resource	19.4	22.3
Equipment	11.8	5.4
Drugs	22.6	26.0
Legal requirements	0.5	0.3

*Values are in Percentage of total.*

Table 2: Components of expenditure

This shows that the cost structure is dominated by what the standard requires in the form of infrastructure.

## Our work is incomplete

We have only estimated the costs of the standards. We have no idea of the benefits arising out of these standards. No studies or estimates about either benefits or costs were released by the government as part of the process of drafting the standards. We

know that infrastructure costs are important, but we do not know if the size of the waiting room affects the quality of medical care. This requires much more research about the benefits each requirement, like a 35 sq.ft. waiting room, bring to the table.

## Conclusion

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Regulations impose costs. Costs are passed on to users. When the benefits to users are more than the costs, the regulations may be beneficial. It is not clear that the standards for basic clinics satisfy this criterion. There are no estimates about the benefits that flow from the standards. It is not clear that mandatory staff or minimum waiting area help induce a positive outcome for patients.

Regulations under the Clinical Establishments Act will have consequences on the price of health care in India. In India, an increase in prices of a few per cent can impact upon millions of users. People excluded from trained medical care may use quacks as a substitute. Such substitutions may have negative effects on health outcomes. More work needs to be done before imposing requirements on regulated entities. The government should carry out research and analysis to be satisfied that each word of each law/standard is justified and the benefits outweigh the costs.

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