

## HEALTH REGULATIONS NEED A BASE TO TOP APPROACH

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Paper - II  
(Governance)

In the last week of May, an incident of a devastating fire in a private neonatal care nursing home in New Delhi shook us all. Political parties began a blame game and the media coverage was intense, going overboard and reporting incorrectly that a number of nursing homes in Delhi function without a licence. Yet, the incident seems to have been forgotten by most even as the parents grieve. Such tragedies are often followed by a question of who should be blamed, completely missing the point that these are almost always the outcome of a systemic failure — in this case, the failure of health-care regulations.

The subject of regulation has always been of interest to health programme managers but, arguably, is one of the weakest points in India's health-care system. It is not as if there are not enough health regulations in Indian States. Rather, it is a problem of excess. Some States have over 50 approvals under multiple regulations, which need to be followed and complied with by every health-care facility. Still, many officials in government, as well as others, believe that the private health sector in India has insufficient regulation.

The other challenge is unrealistic health-care quality standards. Governments at every level in India — national and States — are known to draft policies which are near perfect. One such case is the Clinical Establishments (Registration and Regulation) Act, 2010, enacted 14 years ago, but not adopted by States. This is because State governments, in discussions with stakeholders, have realised that many provisions in the Act are impossible to implement. Another example is the Indian Public Health Standards, or IPHS, drafted by the government for its own health-care facilities and proposed as essential in order to deliver quality health services. The IPHS were first released in 2007 and have been revised twice since then. Yet, in 17 years of existence, only 15% to 18% of government primary health-care facilities in India meet the government's own standards. Clearly, in the efforts to be aspirational, health-care regulations and standards in India have drifted towards unrealistic standards, and are difficult to implement.

### India has a mixed health-care system:

- ❖ There is a binary perception that when it comes to adhering to the rules, the government health sector always does better, and that the private sector always violates them. The fact is that India has a mixed health-care system, where private health-care facilities and providers deliver nearly 70% of outpatient and 50% of hospital-based services. In most States such as Maharashtra or Kerala, the health indicators are better not because these States have outstanding government facilities but because the facilities and clinics in the private sector are fulfilling the health needs of the people. People 'vote with feet' by seeking care at these private health facilities.

- ❖ Yet, when it comes to health-care regulation, there seems to be an unfairness and overzealous attempt to enforce the regulations in the private sector. In 2017, two separate but near identical incidents in two large hospitals in Delhi (a tertiary-care government hospital and a large corporate hospital), had allegedly declared newborn infants as dead; they were alive. This resulted in a temporary suspension of licence in the case of the private hospital, while in the case of the government hospital there was just the setting up of an inquiry committee. Clearly, for effective regulation and adherence, the stakeholder should not feel they are being targeted. In health-care regulation, in the current scheme of things, the burden of responsibility is more on providers and facility owners. Most private nursing homes and clinics have often flagged the issue of approvals being delayed by the authorities for months even when these facilities apply for renewal well in advance. In many examples, applications submitted well on time for renewal (two to three months before the due date), are granted approval months later. The sluggish approval process is a main concern as far as facility owners are concerned.

#### **Affordable care is one need:**

- ❖ The private sector is also not a homogenous entity as there is everything from single doctor clinics, small nursing homes and medium-sized hospitals to large corporate hospitals. Single doctor clinics and small nursing homes are often the first point of contact for access and utilisation of health services in India by middle-income and low-income populations, and are the real lifeline of health services. They deliver a large share of health services at a fraction of cost of that of the big corporate hospitals. Why the parents of the babies opted to go to a private nursing home despite government health facilities with free health services is an issue we must reflect on. The single doctor clinics and nursing homes play a key role in health service delivery in India and make services accessible and affordable. Clearly, there needs to be supportive and facilitatory regulations to serve the public purpose of keeping health-care costs low and affordable.
- ❖ Yet, the tragic incident in Delhi is not something which should be allowed to pass without calm assessment and some concrete plans. First, ensuring quality of health services is essential and the joint responsibility of all stakeholders. However, in an overzealous attempt to ensure having a 'world class tag' or being 'swayed by the lure of medical tourism', the government should not end up making health-care regulations unrealistic. There is a need to formulate guidelines that can be practised and implemented. There is a need to harmonise multiple health regulations and simplifying the application process. Such applications need to be disposed of in a time-bound manner.
- ❖ Second, in regulatory aspects, what is possible for large corporate hospitals may not be feasible for smaller clinics and nursing homes, without escalated cost. Expecting smaller facilities to meet the same standard would make it expensive for the smaller facilities — a cost that is likely to be transferred to patients, making health services unaffordable. There is a need for a differential approach for different types of facilities. Yet, there should be essential and desirable points in each category overseen by regular self-assessment and regulatory visits. If thousands of buildings in the city can have safe elevators, why cannot there be equal emphasis on fire and other safety measures in health facilities? For effective adherence and implementation, the government should consider subsidies and funding to increase adherence to regulations.
- ❖ Third, representatives of doctors' associations and the types of facilities for which regulations are being formed as well as community members should be involved in the process of the formulation of such regulation.
- ❖ Fourth, political loose talk and sensational media headlines might worsen the mistrust of the common man about doctors and nursing homes and may result in increased violence against health-care providers.

### Focus on the primary-care givers:

- ❖ Fifth, and most importantly, India needs to promote single doctor clinics apart from smaller health-care facilities, and nursing homes. These are what deliver primary care and contribute to keeping the cost of health care low. Every such facility and its doctors need to be supported rather than burdened with excess regulations.
- ❖ In the fire tragedy in Delhi, we should not just treat the symptoms but also aim to find and eliminate the root causes. It is a reminder of the need to have simplified and implementable regulations that have been developed with the collaboration and coordination of key stakeholders. There is a need for fairness in implementations, time-bound decisions and the disposal of applications for renewal of licences, promoting smaller health-care facilities with subsidies, and support for increased quality and safety. India's health-care system is already becoming skewed towards admission based in-patient services. It needs to promote providers and facilities that deliver out-patient care at lower costs. This would contribute to the goal of the National Health Policy, 2017 — to deliver health services that should be people-centric, accessible, available, affordable, and have quality. This requires health regulations being drafted from bottom up and not top down, and implemented in a nuanced and calibrated manner.

### Expected Question for Prelims

**Que. Consider the following statements with reference to health regulation in India:**

1. The Clinical Establishments (Registration and Regulation) Act, 2010 is the only approved law at the Center and State level.
  2. Indian Public Health Standards were first issued in 2007.
- Which of the statements given above is/are correct?
- (a) Only 1                      (b) Only 2  
(c) Both 1 and 2              (d) Neither 1 nor 2

**Answer : B**

### Mains Expected Question & Format

**Que.: "Health regulations in India should be designed from the bottom up, not the top down, and implemented in a nuanced and balanced manner." Analyze this statement.**

**Answer's Point of View:**

- ❖ In the first part of the answer, explain the current status of health regulations in India.
- ❖ In the second part, discuss the desired reforms in health rules in India in the context of the statement given in the question and also describe the reforms required to implement them.
- ❖ Finally give a conclusion giving suggestions.

**Note:** - The question of the main examination given for practice is designed keeping in mind the upcoming UPSC mains examination. Therefore, to get an answer to this question, you can take the help of this source as well as other sources related to this topic.