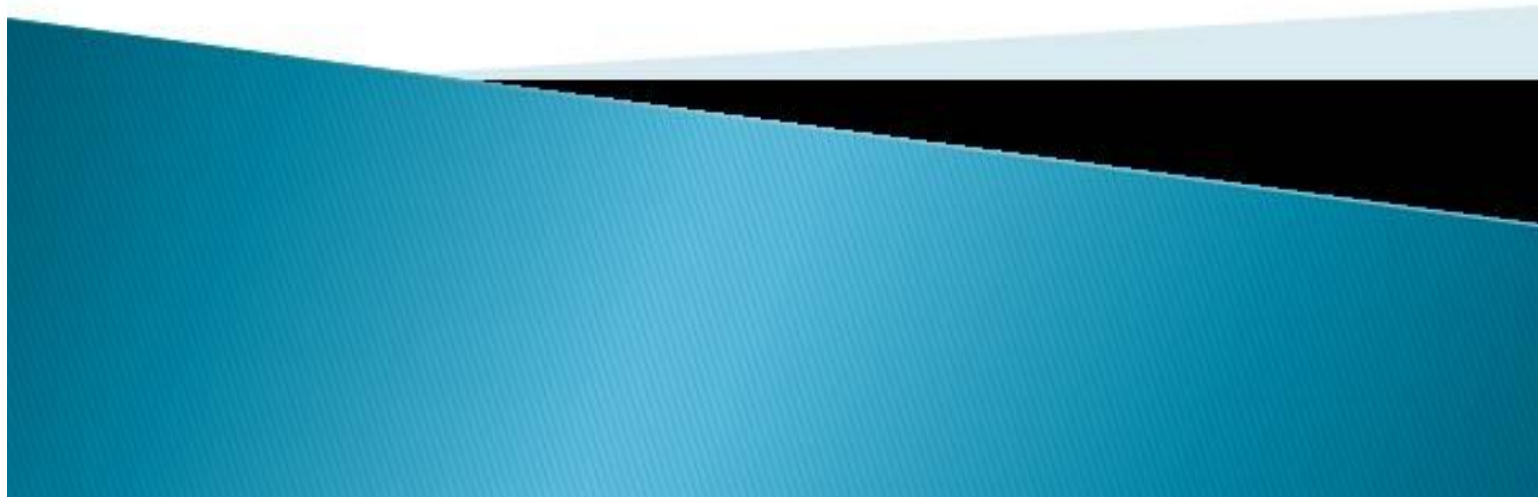


REGULATION OF RATES IN THE PRIVATE HEALTHCARE SECTOR



Regulation of rates in the Private healthcare sector

Justification, feasibility, strategies to address the issue¹

Table of Contents-

1. Introduction.....	2
2. Which variables influence cost of private health care, and how?	3
3. Rate regulation is possible: Promising regulatory actions, practices, and innovations.....	7
4. Possible strategies and actions to regulate the costs of private healthcare-	10

¹ Knowledge product by COPASAH Thematic Hub on Accountability of Private Medical Sector, coordinated by SATHI, India. Drafted by Dhananjay Kakade and Abhay Shukla from SATHI.

A. INTRODUCTION

The People's Health Charter adopted by the global People's Health Movement states that:

Governments have a fundamental responsibility to ensure universal access to quality health care, education and other social services according to people's needs, not according to their ability to pay.

However, creating mechanisms to ensure access to quality health care for all - especially low income and marginalised populations - while protecting them from catastrophic out-of-pocket payments, remains a major challenge. Most LMICs have underinvested in health, many spending less than 3% of their GDP on public health services, leading to their inability to provide adequate care, and pushing people to rely on unregulated private health care despite its high costs.

The very premise of Universal Health Care is – those in need of healthcare should be able to access health care which is effective, without undergoing financial hardship. Yet in the absence of effective regulatory framework, leading to arbitrary costing of health services, the private health sector is increasingly indulging in super-profits based on financial exploitation of patients. Indeed, under the broad rubric of private sector regulation, an issue which requires highest priority attention is regulating the cost of health care.

Taking the case of India, publicly financed health care to cover the entire population in some form has been proposed at policy level since the time of independence, although successive governments have lacked the political will to act on this decisively. India's public health expenditure remains abysmally low at around 1% of the GDP, while accounting to less than one third of total health expenditure. In this situation, private health care providers play a major role in the Indian health system, even though the goals and priorities of private health sector differ significantly from the logic of public health and the UHC paradigm. On one hand neoliberal policies promoting privatisation and active role of the private sector have resulted in cutbacks in the size, capacity, and quality of public sector, on the other hand the state's unwillingness to effectively regulate the private sector is leading to large scale patient's rights violations in private hospitals. Additionally, global evidence suggests that although accountability is a fundamental human right, this is much more difficult to achieve in a privatised or mixed health system. The states where public provision of health care has failed to provide minimum standards of decent universal and affordable health care like India, are precisely those which are least able to monitor and regulate the private health sector. Many academics agree that dependence on the private health sector and privatisation is most risky in societies where public provision is least able to fulfil its human rights obligations²; additionally, competent and highly accessible public sector can generate an environment where private sector is induced to work with reasonable quality of services³.

Why regulation of rates in the private health care sector?

Much of the early literature on the economics of regulation focused on the regulation of public utilities (Spulber 1989; and Price 1994). Empirical studies of regulation examined the control of prices and entry in industries such as utilities, communications, transportation and finance. Kahn (1970, 3) defines regulation as "direct governmental prescription of major aspects of ... structure and economic performance ... control of price, price fixing, prescription of quality and conditions of

2 Consumer directed health care and the disadvantaged- Gregg Bioche (<https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.26.5.1315>)

3 <https://www.thelancet.com/action/showPdf?pii=S0140-6736%2816%2900342-1>

service and the imposition of an obligation to serve...". Manning (1989, 49) defines it as "attempts to govern markets in order to make market participants observe specified standards."

In general, regulation aims to enforce "responsible" conduct on business enterprises, non-profit organizations, and agencies of government and is recognizable by three characteristic elements: (1) a body of governmentally adopted rules or standards prescribing "responsible" behaviour; (2) a cadre of enforcement agents and auditors to monitor, and thereby to deter deviations from these rules or standards; and (3) a schedule of sanctions to be applied to persons or organisations who deviate from the rules and standards to an unacceptable degree (Bardach 1989).

Magalhães Jr. (2006, p.40) presents the issue as follows⁴: "(....) *the term regulation has been used in health care in a broader sense compared to the mere market regulation. It has been related to a function carried out by health systems in general, even in the mostly public ones. It is not only a more classical function of regulation of health market relations as a way of fixing the so-called market imperfections. Due to the diversity in health care systems and to the scope of the state's function in health care, the term clearly assumes a polysemic characteristic.*"

Understanding regulation also entails understanding a well-known vulnerability of regulatory policies and structures- **regulatory capture**. Bennett (1997) asserts that regulatory capture consists of two linked phenomena: first, the interests reflected in the activity of regulators do not adequately represent all those affected by the activity, and second, this inadequacy is due to the difficulty on the part of those authorities in committing themselves to reflecting the interests in question. Elite capture or regulatory capture in many LMICs is an unresolved issue and requires spaces for empowered civic participation and oversight.

Healthcare as a commodity- Is healthcare only a market-based commodity? If not, what are the essential public good characteristics it must retain? And, what role would regulation play to safeguard the public good characteristic of healthcare? Here are some key considerations-

Donaldson & Gerard (1993) challenge unsubstantiated claims that market-style reforms and enhanced role of the private sector in health delivery will create a conducive environment for a *perfect competition* and improve efficiency and quality, by identifying following characteristics of perfect competition : *rationality, non-existence of externalities, perfect information about the market on the part of consumers, small and numerous producers without market power, consumers acting freely in their own benefit. The same authors identify that none of the conditions for perfect competition are found in health care, which makes it difficult to judge value in the health care market, and this would justify state intervention*⁵.

Robert Evans, a renowned economist, warned against considering healthcare as profit-making industry- *"There is in healthcare no 'private competitive market' of the form described in the economics text book, anywhere in the world. There never has been, and inherent characteristics of health and healthcare make it impossible that there ever could be"*.

A pure public good is one for which consumption is nonrival (i.e., consumption by one individual does not reduce someone else's consumption) and nonexcludable (i.e., a consumer cannot be excluded from consuming the good either by having to pay or through some other mechanism) (Folland, Goodman & Stano, 2001). This has been a key underpinning principle in development of health systems in many European countries. In spite of repeated cautionary lines regarding the

4 http://www.scielo.br/scielo.php?pid=S1414-32832006000100003&script=sci_arttext&tlng=en

5 http://www.scielo.br/scielo.php?pid=S1414-32832006000100003&script=sci_arttext&tlng=en

public-good character of the health care, calls for increased price transparency in the private health care are difficult to address, as it is resisted by financially driven commercialism of health care. In healthcare markets, consumers often do not know what type of care will generate significant improvement in their health status and must rely on the providers for advice. Due to asymmetry of knowledge and power between patients and providers, obtaining accurate knowledge regarding the complexity of medical diagnosis and procedures is difficult. The consequence of a lack of information is that most consumers must rely on an informed agent to act as a representative. The agent is usually the physician. However, as Kumaranayake (1998) notes, a doctor is both an economic agent with skills to sell and is a member of a pressure group with interests to defend. However, that latter role should not compromise patients' safety.

Health care providers have a fundamentally different ethical orientation about the appropriate use of health services than economists and business professionals. Key to the idea of universal healthcare is a commitment to equal access to healthcare on the basis of need, and not market performance or person's place and productivity at work. As such, it is not a sector premised on profits; and when access to healthcare is dependent on income, it explicitly legitimises inequalities and exclusion of the poor. If healthcare is considered as a commodity, people who cannot afford it are rendered non-players, and their rights are denied. In spite of capitalist orientation of the state, many European countries established expansive welfare programs, and health markets were controlled by active state interventions like fiscal and monetary policies, investment in the health as a public good, and safeguarding mechanisms for patients.

B. WHICH VARIABLES INFLUENCE COST OF PRIVATE HEALTH CARE, AND HOW?

In the absence of a sound and credible cost standardisation system, health care prices in LMICs like India are often arbitrary, failing to represent actual costs, thereby also failing to provide meaningful expense related information to the patient. As such, consumables such as medicines, stents, implants etc. typically contribute two-thirds to the profit margins of hospitals, with services contributing the rest. Although the variability of the cost of health services is a complex issue, there are at least seven variables that shape the cost of health care in the private sector.

i. Land and infrastructure

Although land and infrastructure is external to the health care system, it seems real estate cost is one of the key determinants of the cost of health care especially in metropolitan cities. Healthcare market in metropolitan cities is characterised by high real estate cost. Perhaps this is also a reason that components such as room rent, packages and consultation have a wide variation across all major cities in India, whereas lab diagnostics and screening have much lower variation across markets. A major challenge for the healthcare industry as identified by some of the big corporate hospitals in India, is to deal with is the high level of capital intensity and long payback periods for new projects. For setting up a new hospital nearly 60-70% of the capital expenditure is required for acquiring land and developing infrastructure. Further, the hospital business also needs capital for upgradation / maintenance / replacement of equipment and expansion. Effectively, burden of the high cost of the real estate in India is being passed on to patients in terms of hospital bed charges.

ii. Medicines and consumables

Institutional bulk purchases have changed the pharmaceutical and medical devices industry drastically. In a report in 2017, the National Pharmaceutical Pricing Authority observed that in order to get a bulk purchase order, the industry is "forced to print higher MRPs to meet the demands of a distorted trade channel without getting any benefits from this artificial inflation." This also meant that the manufacturer who printed the highest MRP price would win the bid, allowing the hospitals

to make extremely high profit margins. Ideally, hospitals should procure medicines based on procurement price and quality; however, with an intention of extracting more profits hospitals are using a maximum retail price (MRP) as a criterion. The NPPA analysis also put out the average price to distributor (PTD) for different types of needles and syringes, their average MRPs, and the difference between. It shows that a 2 ml hypodermic disposable syringe with a needle is manufactured, on an average, for Rs. 1.30 and sold for Rs. 8.52. A 50 ml disposable syringe without a needle is made for Rs. 16.92 and sold at Rs. 97 while a biopsy needle is manufactured for Rs. 1183.76 and sold for Rs. 2179⁶. The National Pharmaceutical Pricing Authority (NPPA) published a report in February 2018 showing that reputed private hospitals in Delhi and NCR were imposing super-profit margins up to 1,700% on drugs, consumables and diagnostics⁷. The data are showing that in yet another instance of inflated pricing, the MRPs bear no relation to the costs of manufacturing," said the All India Drug Action Network (AIDAN), a civil society network that works on health and pharmaceuticals.

iii. Human Resource cost

Healthcare infrastructure in India is under penetrated. With close to 20% of the global disease burden, country holds only 6% of the global beds and 8% of the total workforce of doctors and nursing staff. Further, India has just 0.9 beds per 1000 people, which are significantly lower than the global median of 3 beds per 1000 people. It is well known that super specialty domain of the hospitals bring maximum revenue to their coffers; hence super specialists are high earners within the corporate hospitals, and hospitals make every attempt to retain super specialists to maintain brand equity. The salary gradient between resident doctors, nurses, paramedic staff and specialist doctors is astounding. In tier-4 cities, salary gap between MBBS candidates (junior residents) and DM/MCh candidates (super specialists), with 0-2 years of experience, is significant. Junior residents earn between 40000 to 50000, whereas super specialists earn between 4.5 to 5 lakh per month.⁸ It can be safely deduced that super specialty services add significantly to corporate hospital expenses, and this cost is finally recovered from patients.

Further, gross commercialisation of private medical education is a relatively less focused arena, and there is definitely a causal relationship between the cost of medical education and its implication of the cost of health care. With huge capitation fees that are currently prevalent in the private medical colleges, freshly graduated doctors are under pressure to recover money spent on the education. This situation often leads to gross malpractice and further commercialisation of healthcare. e.g. the draft bill and report on 'National Medical Commission'-2017, explicitly stated that there should be no ceiling or regulation of fees in private medical colleges for the majority of students. There are already indications that lax regulation of fees in private medical colleges may lead to a sharp escalation of medical education cost; recently the fees in Adesh Medical college in Bathinda, Punjab have been increased by a whopping 45%, which has shot up the officially allowed fees to nearly Rs.60 lakhs per year. Furthermore, a draft bill also proposed that 'for-profit entities' including businesses and corporations would be officially allowed to open and run Medical colleges thus legitimising and legalising profiteering in medical education. This is a retrograde step, as until now, only not-for-profit institutions were allowed to run medical colleges.

iv. Profit margins

⁶ <https://in.news.yahoo.com/profit-margins-shoot-1251-syringes-071905959.html>

⁷ NPPA (2018): "Office Memorandum," File No 27(2)/2017-Div-III/NPPA, 20 February, National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India, New Delhi, http://www.nppaindia.nic.in/wp-content/uploads/2019/02/overcharging_Details20022018.pdf

⁸ <http://www.hiimpact.in/Salary-Trends-of-Doctors-in-India-by-Hiimpact-Consultants.pdf>

What could be a “healthy profit” in the private health sector is a contentious question, with deep moral and ethical dimensions. Entry of finance capital, and enhanced commercialisation of the healthcare sector firmly put India on the inverse care law⁹ trajectory, making cost containment mechanisms increasingly difficult to implement. Additionally, regulatory mechanisms can be effectively subverted by extracting profits from other healthcare-related services. This “squeezing the balloon”¹⁰ phenomenon has aptly reflected in the following observation of Investment Information and Credit Rating Agency of India Limited (ICRA) Vice President¹¹ - “regulatory intervention in terms of pricing caps on medicines are expected to continue to exert pressure on the margins in the near term. However, the hospitals may gradually offset these costs over the medium term by general hike in tariffs and by re-looking at the innovative pricing of various procedures, products and services.” Much publicised regulatory action by the Indian Government to reduce the cost of the cardiac stents in reality has not benefitted end users. Intercontinentale Marketing Statistics (IMS) Health in it’s report - ‘Medical Devices in India—Accessibility, Quality and Pricing’, has following observation-“Looking at price reductions (of stents) across levels, it seems like the benefits of decreased price are getting passed from manufacturers to distributors and from distributors to hospitals, but the benefits are not entirely getting passed from hospitals to patients.”. While keeping the cost of stents not beyond the ceiling price as stipulated by the NPPA, hospitals have successfully worked around the cost of other materials and procedures to ensure that their profit remains intact. Indeed, profit margin is a complex issue that requires a comprehensive ecosystem view of the private health sector.

v. Irrational care and unethical revenue targets- Consultants hired by private hospitals have to meet targets for generating revenue by overprescribing diagnostic tests and avoidable surgeries. No data exist on the prevalence of such targets; however, there are some reliable testimonies. “For seven years I had to bear the burden of doing unnecessary investigations and procedures, including angioplasty, under pressure from the management of the hospital,” Gautam Mistry, a cardiologist in Kolkata, told the BMJ.¹² This grim observation has been further endorsed by various other doctors who were interviewed by Dr. Arun Gadre, for the book -Dissenting Diagnosis. In pursuit of higher profits corporate hospitals do not hesitate in setting revenue targets for doctors, and this is a common tactic to push doctors to indulge in range of unethical practices. Needless to say, irrational and unnecessary interventions inevitably escalate the cost of the private healthcare.

vi. Pharmaceutical company - doctor nexus, and kickbacks for referrals

A study in the Journal of Pharmacy and BioAllied Sciences found that 50 of 81 doctors in a Tamil Nadu hospital thought that medical representatives had influenced their prescribing patterns and 51 said that they had received gifts from companies, which shows how drug companies affect prescribing. Globally pharmaceutical companies alluring doctors and hospitals is amply documented, India is no exception to this trend. Drug prescribers in Washington, DC who received gifts from pharmaceutical companies wrote more prescriptions, more costly prescriptions, and more branded prescriptions per patient than colleagues who did not receive such gifts, shows a new analysis based on local and federal database information.¹³ Prescribing branded drugs when cheaper generic variations are available is a common trend in India. Predilection for an expensive branded drug is

⁹ Julian Tudor Hart- <https://www.sciencedirect.com/science/article/pii/S014067367192410X>- The availability of good medical care tends to vary inversely with the need for it in the population served. This inverse care law operates more completely where medical care is most exposed to market forces, and less so where such exposure is reduced. The market distribution of medical care is a primitive and historically outdated social form, and any return to it would further exaggerate the maldistribution of medical resources.

¹⁰ the air moved, but does not disappear, instead moving into another area of less resistance- Wikipedia

¹¹ <https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/hospital-sector-may-see-12-14-revenue-growth-over-5-yrs-icra/articleshow/63534803.cms>

¹² <https://www.bmj.com/content/351/bmj.h4312>

¹³ <https://www.bmj.com/content/359/bmj.j4979>

primarily due to Pharma incentives to doctors. The **Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulation 2002** and **Uniform Code of Pharmaceutical Marketing Ethics**, announced by the Department of Chemicals in 2014, prohibit Pharma companies or their associations, representatives to extend hospitality to health care practitioners. In reality, this norm is often violated while seeking Pharma sponsorship for the medical conferences.¹⁴ A recent research in US has shown that even a single modest meal bought for a doctor by an opioid manufacturer's sales representative is associated with slightly increased opioid prescribing by that physician in the next year. Doctors who received no industry gifts in 2014 wrote a mean average of 134 prescriptions for opioids, while those who did receive a gift wrote 539.¹⁵ Inevitably, sponsored doctors are more inclined to prescribe medicines from particular company than other, even when choice of medicine has a cost implication for patients. The restrictions on Pharma companies from sponsoring doctors would also reduce healthcare costs.

Kickbacks for referrals-'cut practice' as it is commonly called, is deeply embedded in the private healthcare transactions. In 2014, Kokilaben Dhirubhai Ambani Hospital had to apologise to the Maharashtra Medical Council (MMC) for offering incentives to doctors referring patients to the hospital. The cut offered to doctors ranged between Rs 1 lakh and Rs 2.5 lakh.¹⁶ Unfortunately, the Indian Medical Association's (IMA) ban on referral cuts was openly opposed by some of the leading hospital owners and doctors. In a strikingly unapologetic admission and support to cut practice, the President of Pune Orthopedic Society Association of Nursing Homes has said- *"Cut practice — though unethical — can be continued, as it is a question of survival for a freshly-graduated doctors. We are forced to become businessman by society."*¹⁷ Cut practice encourages unwarranted diagnostic tests and procedures. One estimate suggests that stopping cut practice would help reduce patients' expenses by up to 25%.¹⁸ Hence profiteering by drug companies channelized through doctors also inflates costs of health care.

vii. Variation in the condition of the patient

This is one of the inherently variable determinants of healthcare cost, which may result in significant cost variations between estimates and final cost in case of some patients. This is perhaps one aspect of the healthcare where regulatory mechanisms need to allow for some flexibility in case of unexpected complications. This would largely depend on the existing ailment and treating doctors. However, healthcare pricing models developed by health insurance companies and UHC systems average out such variations to reflect the overall costs of providing care despite some variations. It is eminently possible to arrive at transparent average prices that reflect costs of care despite variations.

Regulation of costs is possible by dealing with all key variables

Closer examination of these variables shows that the first three costs (land and infrastructure, medicines and consumables, manpower costs) can largely be standardised while keeping in view the need for categorization of rates according to size of cities, urban v. rural areas, regional variations etc. Remuneration / salaries of specialist doctors and consultants may be an area of some negotiation, but this can be standardised by factoring in basic qualifications, special training and years of experience of any medical professional.

¹⁴ <https://scroll.in/pulse/825813/why-there-is-a-problem-with-pharma-companies-sponsoring-medical-conferences-in-india>

¹⁵ Even a \$13 meal paid by pharma increases doctors' opioid prescribing, study finds <https://www.bmj.com/content/361/bmj.k2256>

¹⁶ http://epaper.dnaindia.com/story.aspx?edorsup=Sup&ed_code=820009&ed_page=3&boxid=38970&id=66509&ed_date=06/25/2014

¹⁷ <https://punemirror.indiatimes.com/pune/civic/Med-groups-up-in-arms-against-IMA/articleshow/37916757.cms>

¹⁸ <https://www.bmj.com/content/358/bmj.j3202>

The next three variables are more interesting since they are less explicitly discussed, though being of great significance in fueling costs of health services. In a publicly managed UHC system, espousing explicit public goals for the entire range of health care providers, these variables need to be either eliminated (irrational care, kickbacks) or capped at zero level / defined modest level (profit margins). It is likely that vested interests in the health care industry may try to keep these variables opaque, or the goal of unbounded profit maximization by health care providers might be defended in a neo-liberal framework. Here the underlying principles of UHC would need to be reiterated by public actors, and the goal of universal access to health care must be made to prevail over unlimited profiteering in public decision making processes.

The last variable can also be dealt with, as evidenced by willingness of large proportion of health care providers to accept standard reimbursement rates when they provide care under various insurance schemes. Hence overall, if a transparent costing procedure is carried out, the prices for health services in the private sector can be standardised. However, this would necessitate curbing of various forms of profiteering and corruption which are widely prevalent today. The issue of regulation of rates in private health care is not a question of feasibility; it is a question of willingness.

Private Health insurance and cost implications

Health insurance is often presented as a solution to avoid catastrophic health care spending. Although there are various insurance approaches, in this section we briefly take note of private, voluntary insurance, which is primarily used by the affording middle class. Various types of health insurance schemes exist in India and can be broadly characterized as community health insurance, commercial insurance and social insurance. Community insurance schemes are typically small-scale operations run by non-government organizations (NGOs) and have a low membership base. The coverage under various community health insurance schemes is 30–50 million. Private health insurance (PHI) is provided by both public and private commercial health insurers and typically covers only hospitalization costs. Private individual health insurance covers a very small proportion of the population (2.1% of health care expenditure in India)¹⁹.

One of the untested assumptions around the PHI is that it offers personalised insurance packages and is efficient in claim settlements. However, this is countermanded by the overwhelming evidence that PHI has a higher administrative cost due to product development as well as advertising and distribution activities; and as a consequence, there is usually a substantial difference in the cost of running a private health insurance compared to a public scheme. Furthermore, providers of PHI have an incentive to be selective about whom to insure. Beyond raising premiums for bad-risk individuals, providers can simply refuse to insure high-risk/high-treatment patients (discrimination). Evidence of market exclusion of bad-risk patients is manifold and difficult to prevent (cream-skimming)²⁰. Additionally, insurance companies put cap on the hospital room rent, and all subsequent charges are linked to the cap. Effectively, even when one has a cashless policy, it might not be entirely cashless and the patient has to pay for various services and items not covered by the policy. Also, if the final bill exceeds the amount approved, the hospital deducts the balance from the deposit. It is also worth considering that the rate of medical inflation is currently around 14 per cent, insurers managed to cap it at 5.5 per cent during 2014-15 for cashless claims, according to data provided by ICICI Lombard, the largest private general insurer.

¹⁹ National Health Systems Resource Centre, Ministry of Health & Family Welfare, Government of India
National Health Accounts Estimates for India, November 2018

²⁰ www.oecd.org/dev/insights

In 2011, the four public sector general insurers which control 70 per cent of the Rs. 20,000-crore health insurance industry fixed the rates for around 42 medical procedures across various categories of hospitals for settling cashless claims.²¹ Given this context, it is ironical that hospital lobbies and doctors who generally oppose any rate regulatory interventions, regularly enter into negotiated rate agreement with the insurance companies. Another problem with private health care insurance is, it primarily covers the hospitalisation cost but does not completely cover the cost of the medicines. This is an important drawback as 72% (74% rural and 67% urban) of OOP expenditures on health is on drugs, and the share of drugs has been considerably higher for outpatient (82%) relative to inpatient visits (42%), a pattern seen in both rural and urban areas and across socio-economic groups.²² Yet another limitation of the private health insurance is a ceiling on the post hospitalisation expenses, and most of the insurance companies are putting a cap at 5% of total sum assured, effectively, patients with low coverage policies inevitably pay much higher amount on the post hospitalisation care.

Further there is evidence that amounts claimed by patients for cashless care covered by insurance tend to be significantly higher than amounts claimed through normal reimbursement²³. This implies inflation of bills by hospitals, when lower level of scrutiny by the insurance company is expected. In summary, out of pocket expenditure might be reduced in some cases but not eliminated through private insurance, and overall costs of care in terms of amounts claimed may actually increase when the patient is covered by insurance. Private insurance may be a stop-gap arrangement for individual families, but it is not a comprehensive solution for containing costs of medical care.

C. RATE REGULATION IS POSSIBLE: PROMISING REGULATORY POLICIES, ACTIONS, PRACTICES, AND INNOVATIONS

A. Examples where the Indian state has played an active role as regulator in the Health care sector

- ◇ In February 2017, NPPA (National Pharmaceutical Pricing Authority), India slashed prices of life-saving stents by over 80% after it capped their retail prices. Before that, drug-eluting stents — the most commonly used in India — were priced upto Rs 200,000. Under NPPA orders, the maximum margin that hospitals and distributors together can have is 8%.
- ◇ Historically, the Drug Price Control Order has regulated prices of medicines included in the National List of Essential Medicines. However these provisions are now being diluted through promotion of market-based pricing instead of cost based pricing as basis for regulation.
- ◇ India has used compulsory license mechanism to force multinational Pharma giant Bayer AG to allow a low-priced local copy of its expensive cancer treatment.

Instances like the above demonstrate that government can effectively safeguard patient's rights by putting cost regulatory mechanisms in place. However, most of these instances are specifically targeted to contain a cost of particular medicines or medical devices. Such targeted cost containment actions do not negate a need for a comprehensive regulatory mechanism to control costs of the services in the private health sector. It is worth noting though that in May 2018, the Delhi State government has proposed regulations that would restrict hospitals and nursing homes

²¹ <https://www.thehindubusinessline.com/money-and-banking/insurers-negotiate-with-hospitals-to-bring-down-rates/article8042278.ece>

²² <https://academic.oup.com/heapol/article/27/3/213/614322>

²³ www.moneylife.in/article/do-hospitals-overcharge-for-cashless-medicaid/23373.html

from marking up prices of several medicines and consumables over 50% from their procurement price in a move to curb alleged profiteering at these establishments. The move came months after a damning report by the country's drug pricing regulator that revealed patients here were paying up to 17 times more for some of these products than the price at which these hospitals purchased them. What Delhi Government is proposing should now be followed up by concrete action within the state, and this deserves to be emulated at the national level.

B. How has Japan contained health care costs?²⁴

The Japanese health-care system has one key feature: tight supply-side control of payment by the fee schedule. Costs have been contained by setting of the global revision rate and subsequent item-by-item price revisions of targeted services and drugs. Fees are generally reduced, but when shortages in specific areas are perceived, they are raised, thus giving an incentive to deliver the service. As such, following are some of the key strategies Japan has used to contain the cost of the healthcare-

- Greater use of outpatient services compared with inpatient care- Japan has the highest per-head number of physician visits of all OECD countries. Although the per-head number of beds is also high, because the bed turnover rate (14.8 per bed per year vs the OECD average of 43.6 per bed per year) and the number of physicians and nurses per bed (27.2 and 117.3 per 100 beds, respectively vs OECD average of 99.8 and 248.9 per 100 beds, respectively) are quite low in Japan, the use of inpatient services is not as high as it seems. The reason why this situation exists is historical: almost all hospitals were established as an extension of physicians' clinics.
- Nationally uniform fee schedule- supply-side cost control is provided by the nationally uniform fee schedule for reimbursement, which is revised at both the global and the item-by-item level. The fee schedule controls the money flowing from all insurance plans to almost all providers. Thus, although Japan has multiple payers (about 3500 insurers) it has only one payment system that is applied across the board. This structure improves equity, since the benefit package is essentially the same for all social health insurance plans, and increases efficiency, since administrative costs are reduced.
- Onsite audits of medical records- Adherence to regulations for billing set by the fee schedule is inspected by peer review of claims filed, which result in a denial of payment for 1.4% of the amount billed. Additionally, on-site audits of medical records are made, with the frequency determined by the provider's past record of compliance. If systematic non-compliance is revealed in the audit, providers have to retrospectively pay back the amount that they had inappropriately billed for the past 6–12 months. Although the primary purpose of the claims review and audits is cost containment, they also serve to control quality by standardising physicians' practice in line with the regulations. An additional measure to contain costs is the restriction of extra billing (billing of services or drugs that are not listed in the fee schedule) to mainly extra-charge rooms and new technology that is still being assessed for efficacy, and the prohibition of balance billing (charging more than the prescribed price).
- Diversity of insurance plans but universal coverage- Japan's achievement of universal health insurance coverage in 1961 was fairly early in the world, notable since its income per person that was half that per person in the UK. Today virtually all Japanese people are covered by social health insurance, through 3500 plans according to where they are employed or where

²⁴ [https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736\(11\)60987-2.pdf](https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(11)60987-2.pdf)

they reside. Japan has also reduced inequities between the different insurance plans by making co-payment rates uniform, except for elderly people and children, and by mandating cross-subsidies among plans to adjust for the different proportions of elderly people enrolled. These efforts have worked towards implementation of egalitarian principles of equal treatment in terms of social health insurance for nearly all Japanese citizens.

- Long-term care insurance²⁵ - The proportion of people aged 65 years and over has nearly doubled in the past two decades, going from 12% in 1990 to 23% in 2010. Since the late 1970s, policy makers in Japan have focused on how to finance health expenditures for elderly people. Japan implemented a public long-term care insurance in 2000 to meet the challenges of its ageing society and to contain health expenditures. Long-term care insurance operates on the basis of social insurance principles, with benefits provided irrespective of income or family situation; it is unusually generous in terms of both coverage and benefit. This policy has gained widespread public acceptance, shown in the doubling of service use and expenditures in the past 10 years, during which health expenditures increased by only 15%.

C. Public participation and social regulation of private health insurance and plans in Brazil

The National Regulatory Agency for Private Health Insurance and Plans (ANS) is the Agency established by the Brazilian Government under the Ministry of Health that operates nationwide to regulate, standardize, control and inspect the private health insurance and plans sector in Brazil. It was established by Act 9,961 in 2000, which defines its spheres of competence. The objective of the Regulatory Agenda is to draw up the schedules for high-priority activities, in order to ensure greater transparency and predictability for regulatory actions allowing society to monitor the commitments that have been pre-established by the ANS²⁶. Key beneficiary focused themes of the regulatory agenda are-

- i. Guaranteed access and good quality care – this is designed to ensure good quality care with timely, adequate access to contracted healthcare services.
- ii. Guaranteed access to information- Endow beneficiaries with information on healthcare and rights, stressing the use of clinical guidelines, and provide information on contracts and correlated documents related to beneficiaries. Rationalize quality indicators, making them more straightforward for consumers.

In addition to above, two important features of ANS are-

- iii. Public written consultations²⁷- Public Written Consultations are discussions of important issues that are open to society, through which the ANS seeks input that will underpin its decisions. This is expected to make government actions more democratic and transparent. Public Written Consultations must include input from individual citizens and specialized sectors of society, such as scientific enterprises, professional entities, universities, research institutes and other representatives of the regulated sector.
- iv. Public Hearings²⁸- The ANS may organize Public Hearings in order to hear the views of society on important matters related to the regulation of private health insurance plans.

²⁵ [https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736\(11\)61098-2.pdf](https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(11)61098-2.pdf)

²⁶ <http://www.ans.gov.br/the-ans/regulatory-agenda>

²⁷ <http://www.ans.gov.br/legislation/public-consultations>

²⁸ <http://www.ans.gov.br/legislation/public-hearings>

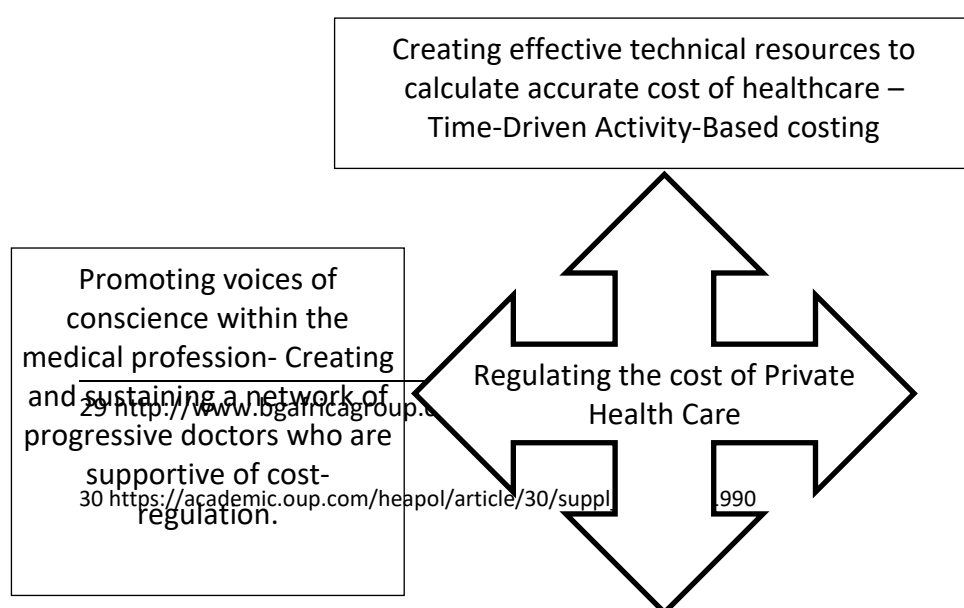
Announced in advance through the internet and in the Federal Government Gazette (DOU), these meetings may be conducted in virtual settings. In order to attend, stakeholders must complete the form made available when these occasions are announced. When registering, people comment on the points they wish to present and identify the institution they represent, if any. The ANS may forward documents related to the issue to the email address on the registration form. If the Public Hearing is held over the internet, access will be open to everyone, with no limits on attendance or prior registration required. After each Hearing, the ANS issues a Public Hearing Report.

Brazilian regulatory processes appear to be highly participatory and thereby more amenable to respond to community opinions and demands.

D. South African legislation governing the health market²⁹

In South Africa, during a period of de-regulation of the health insurance industry during the 1990s, commercial health insurance administrators practiced cream-skimming and risk-rating in order to segment plans and offer cheaper premiums, and also extracted profits from non-profit insurance plans through unethical reinsurance (Doherty and McLeod 2003; Doherty and Steinberg 2003). Brokers were also incentivized by administrators through commissions to 'churn' members between different insurance companies. However, recent amendments to the competition legislation in spite of strong opposition by Insurance companies and private hospitals, have now allowed the Competition Commission to launch a market enquiry, with wide-ranging powers to subpoena stakeholders and demand information on activities (including underlying costs) (Bateman 2013). This is in order to investigate the causes of cost escalation in the private sector, including whether there are unfair business practices by private hospitals (such as collusion by the three dominant hospital chains on prices), health insurance administrators (such as excessive administrative costs) and specialists (who sometimes have a financial interest in the hospital to which they refer or are required to cross-refer to the hospital in which they lease consulting rooms).³⁰

D. POSSIBLE STRATEGIES AND ACTIONS TO REGULATE THE COST OF PRIVATE HEALTHCARE IN INDIA



Using Patient's Rights as a fulcrum to create
social discourse to check super profits in the
private health sector, while demanding
participatory regulatory mechanisms

A. Creating effective technical resources to calculate accurate cost of healthcare

i. Adapting Time-driven activity-based costing in health care to bring in cost transparency^{31 32}

Accurate cost measurement in health care is challenging, first because of the complexity of health care delivery itself. A patient's treatment involves many different types of resources—personnel, equipment, space, and supplies—each with different capabilities and costs. These resources are used in processes that start with a patient's first contact with the organization and continue through a set of clinical consultations, treatments, and administrative processes until the patient's care is completed. The path that the patient takes through the system depends on his or her medical condition. Traditional cost accounting systems accumulate either actual direct costs (job-order costing) or standardized direct costs (standard costing) for each product. In the health care setting, the "product" is patient health. Allocating direct costs is not particularly difficult; one simply sums the costs easily tracked to an individual, such as medications, patient supplies, and surgical equipment. It is the allocation of indirect costs that can prove troublesome. This is generally accomplished by allocating a portion of indirect overhead costs, such as general administrative costs, to each job based on a pre-selected method of allocation. Another method uses a predetermined daily overhead rate, in which overhead is allocated to patients based on the length of the hospital stay. A third method can be called the "mark-up" method, in which a preset percentage of the patient's direct costs are added to the bill to represent overhead. This seems to be the overall trajectory of how costing is done even in the Indian private hospitals. Robert S. Kaplan and Steven R. Anderson have suggested following seven steps for "Time-Driven Activity-Based Costing," in HBR 2004.

Step 1 Select the medical condition

Step 2 Define the care delivery value chain, i.e. chart all key activities performed within the entire care cycle

Step 3 Develop process maps that include each activity in patient care delivery, and incorporate all direct and indirect capacity-supplying resources

31 [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5813634/?log\\$=activity](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5813634/?log$=activity)

32 <https://hbr.org/2004/11/time-driven-activity-based-costing>

Step 4 Obtain time estimates for each process, i.e. obtain time estimates for activities and resources used

Step 5 Estimate the cost of supplying patient care resources, i.e. the cost of all direct and indirect resources involved in care delivery

Step 6 Estimate the capacity of each resource and calculate the capacity cost rate

Step 7 Calculate the total cost of patient care

By capturing all the costs over the complete cycle of care for an individual patient's medical condition, patients can get fairly close estimation of healthcare and will bring in more transparency in the costing methods. It seems system like this will bring more transparency on how indirect cost is allocated and thereby will also partly avoid situations where estimated cost and final cost of treatment does not show significant variation.

Additionally, Kaplan and Porter³³ assert that the existing costing systems, which measure the costs of individual departments, services, or support activities, often encourage the shifting of costs from one type of service or provider to another, or to the payer or consumer. The micromanagement of costs at the individual organisational unit level does little to reduce total cost or improve value—and may destroy value by reducing the effectiveness of care and driving up administrative costs. They further assert that the current costing is based on the use of highly aggregated data for estimating costs and the deeply flawed assumption that every billable event in a department has the same profit margin. Reimbursement-based costing also buries the costs of valuable but nonbillable events, such as patient consultations, in large overhead pools that are allocated arbitrarily and inaccurately to billable events.

Kaplan and Porter advise that we need to abandon the idea that charges billed or reimbursements paid in any way reflect costs. The cost actually depends on how much of a resource's available capacity (time) is used in the care for a particular patient, not on the charge or reimbursement for the service, or whether it is reimbursed at all. Direct costs of patient care, such as nurses, physicians, and consumable supplies (drugs, bandages, and syringes), ought to be assigned more accurately to individual patients. However, allocating the costs of indirect and support units cannot be done except with crude, arbitrary methods, often dressed up to look sophisticated. The usual method is spread overhead and support costs across each department's billable activities, using metrics such as the size of direct costs, headcount, length of stay, assigned physical space, number of patients, number of procedures, or costs-to-charge ratios. However, such a method is arbitrary and proven to be mostly ineffective. Kaplan's emphasis that the existing cost system of allocating support-department costs primarily based on length of patient stay, and not on the patient's use of support resources is a real problem in arriving at the exact cost and accurate allocation of indirect cost.

(Details can be accessed at- <https://hbr.org/2011/09/how-to-solve-the-cost-crisis-in-health-care>)

B. Legal Route: Effective Clinical Establishment Acts³⁴

As per Constitution of India, health is a state subject. Hence, state governments have the prerogative to enact legislations to regulate private hospitals. However, the Clinical Establishments Act, 2010 was enacted by the Government of India for registering and regulating all types of public

³³ <https://hbr.org/2011/09/how-to-solve-the-cost-crisis-in-health-care>

³⁴ Troubling realities of private hospitals in key South Asian countries- SATHI publication

and private clinical establishments in the country, including single-doctor clinics. This is a kind of model act and it is adopted by 11 state governments and union territories (UTs) administrations. The Act provides for the creation of a regulatory authority at the national and state levels with minimal representation to civil society groups and overwhelming representation to medical community in Clinical Establishment Councils. Key elements in the Act include the grading of clinical establishments, adoption of standard treatment guidelines, minimum physical standards, rate display and rate standardisation. However, there is no provision for patient's rights, grievance redressal mechanism for patients. There is no specification of dedicated structure, additional staff (and related dedicated budget) for implementation of clinical establishment act. The process of standards formulation is highly centralised at national level which may not augur well for local conditions in a huge and diverse country like India. Now, display of patient's rights charter has been incorporated into draft minimum standards.

Despite of its overwhelming representation to medical community in councils, this act met with severe resistance from medical community. Hence, even after eight years of passing the legislation, its implementation has largely remained on paper especially since the required standards have been displayed on the health ministry website since 2014, but are not notified as of May 2019! The key provision for regulation of rates in private hospitals appears to have been sidelined, since the onus for the complex task of developing standard costs has now been shifted to state governments. As a result, the Clinical Establishments (Registration and Regulation) Act remains largely on paper, encouraging many corporate and large private hospitals to continue with overcharging and other exploitative practices.

Overall despite having several positive provisions, effective implementation of CEA has been stalled in India due to continued resistance by lobbies of the private medical sector. Ensuring fair, non-corrupt implementation of such regulations without harassing the medical community, yet at the same time offering justice to aggrieved patients and preventing elite capture of the process is the unfinished agenda to regulate the private health sector, which now needs to be taken forward.

C. Strengthening the discourse on patients' rights

Several frameworks and justifications can support patients' rights. However, most of them are rendered ineffective because of poor adherence and weak oversight. In last five years under the aegis of Patient's Rights Movement, SATHI and Jan Swasthya Abhiyan had organised regional workshops and dialogues, which initiated much needed social discourse on the private sector regulation. This was not only to identify problems but also to foreshadow possible solutions to the existing problems. Patient's Rights has been an effective cornerstone for overall struggle to regulate the private sector. Some of the activities on Patients' Rights that were conducted in Maharashtra and at national level in India by Jan Swasthya Abhiyan offer a glimpse into possible strategies for social mobilisation and advocacy.

D. Promoting voices of conscience within the medical profession

In October 2018, a group of doctors and nurses in Quebec (Canada) had called for a cut in their wages to help mitigate the squeeze on public health service budgets. More than 750 physicians, residents and medical students in the French-speaking region have signed an online letter opposing a recent salary hike negotiated by their medical unions. "These increases are all the more shocking because our nurses, clerks, clerks and other professionals face tough working conditions, while our patients live with the lack of access to required services because of the drastic cuts in recent years and the centralization of power in [Quebec's] Ministry of Health," reads the letter. "The only thing that seems to be immune to the cuts is our remuneration." Radical as it may seem, voices of conscience within the medical profession are not rare. In India, the path-breaking book 'Dissenting Diagnosis' was published in India in 2016. The book is based on testimonies of 78 'whistleblower' doctors. This book is possibly the first of its kind where critical introspections of doctors in the

private health sector are documented. Publication of this book also led to the formation of the ***Alliance of Doctors for Ethical Healthcare*** (<http://www.ethicaldoctors.org/index.php/mission/>). ADEH aims to foster rational, ethical practice, and de-commercialise the profession in the interest of ordinary people, patients and rational doctors, and is actively concerned with bringing down costs of care along with various other policy concerns.

Conclusion

George Orwell famously stated that myths which are believed in tend to become true. The problem with the private health sector is that its pervasive power allows some deeply entrenched popular myths to stay afloat. e.g. quality care is bound to come at higher cost, private sector is more efficient, costing in the private health sector is transparent, for the private sector all kinds of profit making is justified, etc. Now such popular myths and their power are being questioned by group of committed activists, who have a clear analytical framework as well as action logic. Although, the struggle for regulation of the private health sector and cost-containment is at a nascent stage, we have taken small but significant steps forward. The movement for patient's rights and regulation of the private health sector is reaffirming what Mark Planck said more than a century ago- *When you change the way you look at things, the things you look at change.*