The Rise Of The Regulatory State In The Chinese Health-care System

Jiwei Qian, National University of Singapore
Chapter 1

Introduction

With a rapidly ageing population, the health-care system has become increasingly important in China. Health expenditure amounted to over RMB4 trillion in 2015, or 6% of gross domestic product (GDP),¹ compared to about 4% in 1997. The share of health expenditure in GDP is expected to reach 8.4% by 2030.² The government has also spent a huge sum of budget on health care. In 2015, government health budget amounted to over RMB1.2 trillion, accounting for about 7.12% of total fiscal expenditure compared to 4.4% in 2008. Between 2009 and 2015, total government expenditure on health reached RMB5.9 trillion, compared to RMB1.4 trillion between 1999 and 2008.³

Besides spending directly on health care, the government plays another important role in the health-care system as the regulator. Notably, since the 2000s, a number of regulations in social health insurance, health service quality, pharmaceutical sector, public health, antitrust and other regulations have been implemented. New regulatory agencies have been established and existing regulatory agencies have been granted more

³ *China Health Statistical Yearbook*, various years, and *Statistical Communiqué on Health and Family Planning Development in China, 2015*. 
authority. For example, China Food and Drug Administration (CFDA) was promoted from a vice-ministerial to ministerial level agency in 2013. Local agencies of CFDA have been established in all provinces, in over 70% of cities and 30% of counties.\(^4\) Regulatory reforms in the arena of public health have also been initiated, particularly at the local level. For example, in June 2015, Beijing’s smoke-free regulations, the country’s strictest tobacco control law, took effect, mandating all indoor and many outdoor public spaces in Beijing 100% smoke-free.\(^5\)

### Why are Regulations Necessary for the Health-care System?

Regulation refers to “rules developed and enforced by administrative agencies”.\(^6\) More specifically, regulation can be “government actions to control price, sales and production decisions of firms in the ‘public interest’”.\(^7\) In the literature of comparative economics, marketisation in a transitional economy such as China’s goes hand in hand with the expansion of rule-based legal institutions.\(^8\) Regulation together with litigation can be used to correct market failures such as externalities and asymmetric information in the health-care system.\(^9\)

---

Market failures are prevalent in the health-care system in general.\textsuperscript{10} Two types of market failure are highlighted here. First, information is asymmetric between patients and doctors, and between insurers and hospitals. For example, since patients and insurers do not have medical professional training, the quality of health-care service is not known and even observable for them, and the effects of pharmaceutical products are not fully understood by patients. Second, externalities for many public health issues are aplenty. For example, the social costs of smoking are much higher than the private costs of smoking as many people suffer from second-hand smoke.

Regulations are very useful for addressing market failures in the health-care sector.\textsuperscript{11} First, regulations can be considered as a mechanism to internalise the externality so as to equalise private and social costs. For example, regulations to ban second-hand smoke can reduce the externality. Second, compared to litigation, the cost of the enforcement of regulations can be lower since regulations require agents such as doctors or pharmaceutical producers to fulfil certain quality requirement ex ante and service providers will be punished if those quality requirements for health-care services are not fulfilled properly. These ex ante requirements are expected to be easier to be verified compared to ex post evidences required for litigation.\textsuperscript{12}

Third, regulations change the expectation as well as behaviour of agents in the health-care system when there is asymmetric information. Coordination among agents will be more effective. Fourth, the quality of health-care services and pharmaceutical products is expected to be able to reach a threshold level with regulations, even when patients do


not know the quality of services. Further, in principle, a rapid development of the private sector in the health-care system could be expected as the quality of services and products provided by the private sector has to meet the requirements stipulated in the regulations.

**Literature on regulation**

From the recent theoretical and empirical research, state capacity, which is defined as an “institutional capability to carry out various policies that deliver benefits and services to households and firms”\(^{13}\) is pivotal to both economic and social development.\(^{14}\) In particular, the government as one of the most important market-supporting institutions to regulate market is essential for achieving a more efficient allocation of resources. Financial and human capital resources of the government regulatory agencies are critical for implementing regulations. A regulatory state, in this case, depends on the government capacity to implement and enforce regulations.

However, there is also an important tradition in law and economics as well as “public choice” in which the commitment of government officials to public interests is under question. In this literature, government officials are expected to be self-interested and regulators are subject to “capture” by various interests groups.\(^{15}\) Here, “capture” refers to the situation in which regulators represent the interests of the regulated. Even the federal judges in the United States may make decisions on the basis of their own preferences and interests.\(^{16}\) In this case, to build up a

---


regulatory state, incentives of the regulators must be taken into account.

Importantly, institutional arrangements for policy implementation and design are also argued to be relevant by some scholars. In particular, the conceptual framework of “Fragmented Authoritarianism” has been used to understand the ineffectiveness of policymaking in China. According to this framework, the fragmentation of the decision-making authority has led to a situation where interests and information become parochial. In consequence, policymaking and implementation, particularly with regard to economic policy implementation, was not very effective. Recent research has shown the relevance of “Fragmented Authoritarianism” in social policy implementation in China. Some peculiarities in policymaking such as logrolling have also been observed in social policymaking in China. Further, in the process of transition to the market economy, regulations may also be considered as a substitute for the informal institutional arrangements in contract enforcement and dispute resolution.

17 For example, see Qian Jiwei “Improving Policy Design and Capacity from Local Experiments: Equalization of public service in China’s urban-rural integration pilot”, *Public Administration and Development*, vol. 37, no. 3, 2017, pp. 51–64.
20 For example, see Qian Jiwei and Mok Ka-Ho, “Dual Decentralization and ‘Fragmented Authoritarianism’ in Governance: Crowding out expansion of social programmes in China”, *Public Administration and Development*, vol. 36, no. 3, 2016, pp. 185–197.
22 For example, see a recent study by Scott E Masten and Jens Prüfer, “On the Evolution of Collective Enforcement Institutions: Communities and courts”, *Journal of Legal Studies*, vol. 43, no. 2, 2014, pp. 359–400.
Arguments of this Book

In this book, the recent development of the regulatory system in different policy areas of the Chinese health-care system will be discussed. This book will review policy development in the area of regulatory reform after a number of regulatory initiatives have been launched and several regulatory agencies established since the 2000s.

This book also highlights some important constraints in the development of the regulatory state. First, the author argues that the low capacity of regulatory agencies in both the central and local governments certainly is one major constraint. For example, there has been a shortage of manpower at the CFDA. Compared to the over 3,000 employees who work on the approval of new drugs in the Food and Drug Administration (FDA) in the United States, there are only 89 people performing the same task in the CFDA and with a queue of over 18,000 applications by the end of 2014.23 At the local level, the shortage of resources is even more striking. For example, in Chongqing, a city with over 30 million people, the number of local CFDA staff was 22 in 2014.24

Second, in many cases, the incentives imposed by the regulators are not compatible with the development of the regulatory state. For example, the annual revenue of the pharmaceutical industry has reached RMB2.6 trillion in 2015 and is expected to hit RMB3 trillion in 2016.25 For many provinces, the tax revenue from the pharmaceutical industry is significant for local fiscal revenue. Local protectionist behaviours in the pharmaceutical industry have been observed in the

government procurement process as well as other areas of regulatory policy enforcement. In this case, regulation enforcement may be undermined by local protectionism. Another example is related to medical malpractice dispute resolution. For many local governments, social stability may still be one of the highly prioritised policy targets. Protesters involved in disputes concerning medical malpractices have the potential to negatively impact on the local performance on social stability.

Local governments largely prefer to employ more flexible dispute resolution mechanisms to reach a quick settlement with patients compared to enforcing malpractice dispute regulations.

Third and importantly, institutional arrangements are very relevant to the emergence of the regulatory state in China. The institutional structure of regulatory agencies is usually fragmented, both horizontally and vertically. For example, CFDA is not the only regulator for the pharmaceutical sector. The National Development and Reform Commission (NDRC), State Ministry Administration of Industry and Commerce, as well as National Health and Family Planning Commission are also involved in regulating the pharmaceutical sector. Different regulatory agencies have different objectives; in the multiple dimensions of regulatory objectives, the enforcement in those dimensions with a lower priority may not be very effective. In a fragmented


regulatory system, blame-shifting and other opportunistic behaviours may be observed among the regulatory agencies.29

Many regulatory agencies have also decentralised institutional arrangements at the local level. The regulators who interact with firms and hospitals are usually from regulatory agencies at the county/city level or even lower. Such a decentralised institutional structure may undermine the regulatory capacity since the economies of scale in professional expertise and other aspects are not exploited fully.30

Interestingly, various institutional arrangements have been employed to address both capacity and institutional constraints of regulatory agencies. One example is to hold regular joint conferences (Lianxi Huiyi) on regulation in the pharmaceutical sector among relevant regulators and other stakeholders.31 This solution improves the communications among regulatory agencies. Another example is to initiate small leading groups on implementing tobacco control policies. A small leading group consists of representatives from various ministries/regulatory agencies and a coordinator will set the policy agenda. Small leading groups can also be interpreted as a top-down solution to solve the coordination issues. Recently, to address the issue of policy ineffectiveness as a result of fragmented departmental interests, a guideline from the State Council has been released to mandate that all ministries must endorse documents within two working days of discussion and reaching a consensus at the executive meetings of the State Council.32

Similarly, a performance evaluation system has been applied to address the incentives of local officials. Under this performance evaluation system, appointment, promotion and demotion of local

31An example of this institution is discussed in Gilli Mario, Li Yuan and Qian Jiwei, Logrolling under Fragmented Authoritarianism: Theory and evidence from China.
bureaucrats is decided according to whether they have fulfilled the upper level government’s requirements for various policy targets. However, these institutional responses to the incentive and institutional structure may also have unintended consequences. For example, local officials may direct most of their efforts and resources to performance indexes which are more measurable and more rewarding and at the expense of other performance indexes.

By reviewing regulatory initiatives in different areas in the healthcare system, this book attempts to connect recent academic research in economics and political science with policy development in the Chinese health-care system. While there are a small number of studies on the regulations in the Chinese health-care system, this book contributes to the literature in three areas. First, while more regulations have been passed, by reviewing recent cases in the Chinese health-care system, this study supports the literature that the capacity and incentives of the regulatory agencies matter in the implementation and enforcement of the regulations. Second, this study underlines some institutional arrangements in China which are particularly important to configuring the capacity and incentives of the regulatory system.

34 Qian Jiwei and Mok Ka-Ho, “Dual Decentralization and ‘Fragmented Authoritarianism’ in Governance”.
Third, by focusing on the case of China, this book also contributes to the literature by laying out institutional reasons for the ineffectiveness of regulatory reforms in China.

There are two possible explanations to these institutional constraints of regulatory reforms. One explanation is from the macro level. Regulatory reforms are usually second best and policymakers have to trade-off between various policy targets at times. Occasionally, institutional arrangements under these reforms also have unintended consequences. For example, the performance evaluation system encourages officials to be accountable to upper level governments but local officials do not have the incentives to work on unrewarding tasks and tasks which are difficult to be measured. New (informal) institutions initiated from recent reforms may also crowd out the original (formal) institutions (e.g. the people’s mediation ‘renmin tiaojie’ as an informal medical malpractice dispute resolution).

The other explanation is from the micro level. Some institutional reforms may not be as effective as expected since people’s behaviour remains unchanged after these institutional reforms. If the policy implementation process is interpreted as a game, these institutional changes are not credible for players whose actions remain the same after the implementation of the institutional reforms. This explanation is consistent with the recent research in law and economics, which highlights the importance of the belief and value system.30

The institutional constraints of regulatory reforms as described in this book are compatible with both of these explanations. Further research is needed for detailed discussions in these two directions.

The policy areas covered in this book is listed in Table 1-1. Five policy areas will be discussed in the main body of the book, while Chapter 2 gives an overview of the Chinese health-care system, in

---

particular, the evolution of the system since the health reform in 2009. Chapter 3 discusses the regulations in the pharmaceutical sector including issues such as price control, new drug approval, essential drugs and distribution of drugs. Competition policy is expected to be an important policy area given the ever-increasing economic size of China. Chapter 4 discusses the recent development of the competition policy such as anti-monopoly law and its implications for the health-care sector.

Regulatory policies in social health insurance are the focus of Chapter 5 and affordability of health care is the major policy target for social health insurance. Quality of health care is another important policy area for regulation and Chapter 6 discusses the development of resolution mechanisms for medical malpractice disputes in China. With the emergence of the regulatory state, the entry of the private sector in the health-care system is expected. Chapter 7 discusses this topic in detail. Chapter 8 focuses on an area in public health regulation, namely, tobacco control, to illustrate several important issues in public health regulation. Brief conclusions and some discussions about the implementation of regulatory policies in a broader context are presented in Chapter 9.

Table 1-1: The Structure of the Book

<table>
<thead>
<tr>
<th>Policy Area</th>
<th>Topics</th>
<th>Chapters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical regulations</td>
<td>Pharmaceutical sector</td>
<td>Chapter 3</td>
</tr>
<tr>
<td>Market regulations</td>
<td>Competition policy</td>
<td>Chapter 4</td>
</tr>
<tr>
<td></td>
<td>Entry of the private sector</td>
<td>Chapter 7</td>
</tr>
<tr>
<td>Regulations for social programmes</td>
<td>Social health insurance regulation</td>
<td>Chapter 5</td>
</tr>
<tr>
<td>Regulations for dispute resolution</td>
<td>Medical malpractice dispute resolutions</td>
<td>Chapter 6</td>
</tr>
<tr>
<td>Public health regulations</td>
<td>Tobacco uses</td>
<td>Chapter 8</td>
</tr>
</tbody>
</table>