

Robson Rocha de Oliveira
Paulo Eduardo Mangeon Elias

Healthcare regulatory concepts in Brazil

ABSTRACT

The healthcare regulatory concepts used in Brazilian scientific publications on healthcare management were reviewed. A typo-logical classification for regulatory concepts was developed from the most current ideas in five disciplines: life sciences, law, economics, sociology and political science. Four ideas stood out: control, balance, adaptation and direction, with greatest emphasis on the technical nature of regulation. The political nature of regulation was secondary. It was considered that discussion of healthcare regulatory concepts was connected with comprehension of the role that the state plays in this sector. De-finition of the forms of state intervention is the key convergence point between the different ways of conceptualizing healthcare regulation.

DESCRIPTORS: Health Care Coordination and Monitoring. Health Law. Health Public Policy. Health Systems. Health Management. Unified Health System. Review.

INTRODUCTION

There has been growing interest in issues relating to regulation, especially in the healthcare sector. Both in developed and in emerging countries, healthcare regulation has been a topic of debates relating to facing up to the main challenges of healthcare systems. However, the concept of healthcare regulation has been used in very diverse manners, with a variety of meanings, approaches and purposes, among which some have been interrelated and others, divergent.⁵

Notwithstanding the divergences between different authors, healthcare regulation has frequently been discussed in the context of privatization and mercantilization of healthcare systems. From this point of view, regulation has been seen to be a potential response for facing up to issues of different natures in healthcare systems, such as private production, funding and provision of healthcare services.¹⁰

In healthcare systems, evolution of the function of regulation has not come from straight-line progression from one mechanism to the next, but from a mixture of regulatory tools that have been developed over the course of the history of healthcare systems.¹⁶

According to the Annual Report for 2000 from the World Health Organization,^a regulation is a function of healthcare system governance. It is linked to the state's function of organizing reports on production and distribution of healthcare resources, assets and services.

Faculdade de Medicina. Universidade de São Paulo. São Paulo, SP, Brasil

Correspondence:

Robson Rocha de Oliveira
R. Dr. Ovídio Pires de Campos, 225 – 6º andar
Cerqueira César
05409-012 São Paulo, SP, Brasil
E-mail: rroliveira.robson@usp.br

Received: 9/16/2011

Approved: 1/8/2012

Article available from: www.scielo.br/rsp

^a Organização Mundial da Saúde. Relatório sobre a saúde no mundo 2000 - melhorar o desempenho dos sistemas de saúde. Geneva; 2000.

Increased presence of the private sector and incorporation of market mechanisms in healthcare systems are among the repercussions of the mercantilization process that has taken place within the context of transformations of the state.¹⁹ The aim behind incorporating market mechanisms has been to achieve administrative autonomy, i.e. increased capacity to make decisions at institutional level.¹³

The way in which healthcare regulation has been conceived has been influenced by the context of contemporary regulatory reforms of healthcare systems.⁷ Consequently, adequate regulation by the state is needed in order to ensure that decisions made remain consistent with the public interest. Healthcare regulation should therefore be understood from the way in which the state's authority is wielded.¹⁶

The concept of healthcare regulation in Brazil is based on control and auditing activities carried out mainly on private providers contracted by the social security system. Thus, it can be seen that healthcare regulation in Brazil has, since its outset, been concentrated on the activities of private-sector healthcare service producers.

The aim of this review was to identify regulatory concepts used in the Brazilian scientific literature on healthcare management.

METHODOLOGICAL PROCEDURES

This review was conducted in two stages. A typological classification for regulatory concepts was firstly formulated, and then the healthcare regulatory concepts used in Brazilian scientific papers were classified and analyzed, taking the regulatory ideas of this typological scheme as a reference point.

To draw up the typological classification for the regulatory concepts, a critical non-systemic review was conducted, covering the last four decades, in order to identify the key ideas of the regulatory concepts used in the following disciplines: life sciences, law, economics, sociology and political science.

Brazilian scientific papers on healthcare management that were indexed in the search source of the Virtual Health Library were selected (*Literatura Latino-Americana e do Caribe em Ciências da Saúde*, Lilacs). Literature on health sciences published in other countries was selected using Medline and SciELO Public Health.

The type of paper chosen was complete articles. Other types (theses, monographs and unconventional publications) were excluded. Only articles with a complete text, in Portuguese, which had been published in Brazilian journals, were selected.

This investigation was carried out by searching for the term “regulation”, using the word method in the title,

abstract and subject/subject descriptor fields, covering the period from 1994 to 2008. It resulted in identifying 735 complete articles. From these, 280 in Portuguese that had been published in Brazilian periodicals were selected. From reading the abstracts of these articles, 43 articles with a direct relationship with the topic of healthcare management were selected (Figure 1).

REGULATORY CONCEPTS: FUNDAMENTAL IDEAS

A wide variety of regulatory concepts based on different ideas and theoretical reference points could be identified.

Dictionaries from the 19th century show that use of the term “regulator” preceded use of “regulation”. In the 18th century, regulator was a term used in watchmaking, economics, politics and also celestial mechanics. This term only started to have special use in biology and the social sciences during the 20th century.⁴

The term “regulator” was introduced into the field of mechanics between the 17th and 18th centuries, with the meaning of devices for controlling machine movements. Thus, the concept of regulation in the 17th century was applied in technical fields,⁷ and it can be deduced that the initial ideas about regulators and regulatory action are derived from the concepts of control systems.

The epistemological status of regulatory concepts has been little established, and their definitions vary according to the authors. Even today, it is very difficult to propose a unified definition of these concepts. Nonetheless, it can be inferred that the idea of regulation is in line with the notions of systems and complexity.¹⁵

Biological regulation includes many ideas, and the following ideas stand out: function of repair or detection of an effect; function of detection of a deviation or difference in relation to a given reference point; and function of correction of an effect.¹⁵

Regulatory phenomena exist in relation to different levels of organization of the living world (ecosystems,

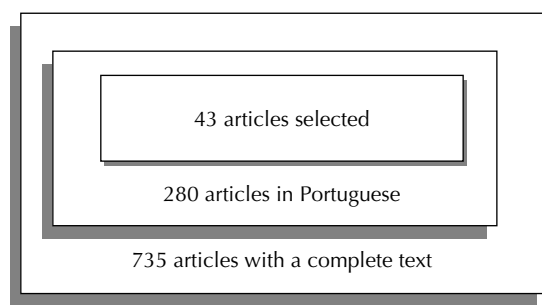


Figure 1. Representation of the selection of articles.

organisms, cells and molecules). Use of a given biological regulatory concept makes the assumption that the living being can be regarded as a system. The term “system” itself indicates that several mechanisms in a dependent relationship that aims towards achieving a certain effect are involved.¹⁸

In law, regulation is the activity that consists of ensuring the balance between the rights and obligations of each individual that was intended by a law. At the same time, regulation brings the idea that the state’s role is to directly command the social players, establish the “rules of the game” and ensure that these are respected.⁶

The term “regulation” has been seen in Brazilian law from the time of the state reform movement of the 1990s. As a result from privatizations of state companies and maintenance of the idea of competition between concessionaires providing public services, the view taken was that it was necessary to regulate activities performed by concessionaires in order to ensure regularity of service provision and competition on a level playing field.⁸ Thus, in Brazilian law, the concept of regulation has been applied mainly within the sphere of the state’s attributions and their interference with the economy.

In the field of economics, regulation is understood as restriction of market activities imposed by the state. Baldwin & Cave¹ described four models of economic regulatory action that involved direct intervention by the state: i) selective model, imposed only to correct market failures; ii) directive model, in which the state is a purchaser or regulator, in order to stimulate certain types or standards of service; iii) restrictive model, which limits what is made available on the market; and iv) prescriptive model, which defines the criteria for service provision on the market.

From the reference point of political economy, regulation denotes a dynamic process of adaptation of production and social demand, resulting from a conjugation of economic adjustments linked to a given configuration of social relationships.¹⁶ Regulation expresses the idea of coherence and compatibility between the structures of offer and demand, in dynamic interaction. Therefore, regulation is not simply a state of static equilibrium, attainable through market mechanisms, as is advocated in the more traditional approaches of economic theory.^{2,3}

Discussion on regulation in the social sciences correlates with one of the fundamental issues of sociology, i.e. how relatively durable social groups or societies can exist despite the great variety of interests that their members have.¹²

Regulation in political science emerged as a synonym for order and equilibrium. The notion of regulation is confounded with the definition of political power, since it represents a way of conciliating conflicts.¹⁴ Hence, regulation is the essential function of political power, which is taken to mean the activity of organizing decision-making processes.

Therefore, certain important matters need to be taken into consideration in order to define regulation. Firstly, this is a polysemic concept and, thus, more precisely, plural concepts of regulation exist, rather than a single kind of regulatory concept. Secondly, the challenge of harmonizing interests of such diverse and even contradictory nature can be highlighted (among others, these include economic versus social interests and public versus private interests).

TYPOLICAL CLASSIFICATION OF REGULATORY CONCEPTS

From the different ideas relating to use of regulatory concepts, four fundamental notions stand out, namely: control, balance, adaptation and direction (Figure 2).

The idea of control has been identified as one of the first and most frequently used notions relating to the concept of regulation. This idea makes it possible to envisage regulation as an activity of adjustment and rule-setting.

From applying the notion of regulation in the field of life sciences, incorporation of another important idea can be highlighted: the idea of balance. This idea is linked to another two: conservation and correction. It should be noted that use of this idea in regulatory concepts has already become disseminated into a variety of disciplines, such as economics, sociology and political science. These disciplines incorporate regulatory concepts and have also imported concepts relating to systems (economic, social and political).

More recently, and notably influenced by theories of cybernetics and complexity, regulatory concepts

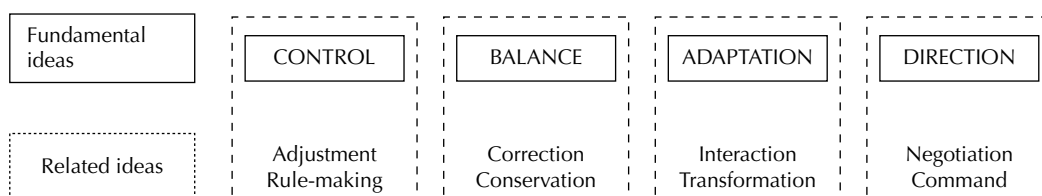


Figure 2. Fundamental ideas relating to regulatory concepts.

have also come to express the idea of adaptation, supported by the ideas of interaction and transformation. Regulation has gained a new dimension linked to the notion of transformation (influence of theories on transformation systems).

Lastly, the idea of direction reveals the interface between this concept and the political domain. In this regard, regulation has an important role in decision-making processes and in public policy formulation processes, through correlations with two other ideas: the ideas of negotiation and command.

The first two ideas contained in this typological classification for regulatory concepts (control and balance) are associated with the more operative aspects of regulation: adjustment, correction and restriction. The third (adaptation) presents an intermediate position between the technical and political dimensions, thereby triggering the transformatory capacity of regulation. The idea of direction shows the political nature of regulation, which correlated with the capacity to organize and wield power.

However, the evolution of regulatory concepts has not been linear, since development of the ideas connected with the concepts has not taken place in successive stages of incorporation and supersession. The new ideas have not replaced the preceding ideas, even though they may have transformed them. Thus, although regulation can be understood from the idea of adaptation or transformation, the idea of control continues to be applicable.

HEALTHCARE REGULATORY CONCEPTS IN BRAZIL

The theoretical reference points identified in healthcare regulatory concepts in Brazilian published papers were of varying nature. On the one hand, this diversity favors discussion of distinct aspects of regulation, but on the other hand, it reinforces the importance of understanding the ways in which regulation is conceptualized.

Analysis on the articles studied showed that there were two distinct publication periods. The first was from 1994 to 2000, marked by lower production of articles on healthcare regulation. In the second period, from 2001 to 2008, there was a progressive increase in the quantity of such papers, especially in 2008, when an issue of the journal *Ciência & Saúde Coletiva* focusing on the supplementary healthcare sector in Brazil was published, with several articles on the matter of healthcare regulation.

The journals with the greatest numbers of published papers, in decreasing order of frequency, were: *Ciências & Saúde Coletiva*, *Cadernos de Saúde Pública*, *Interface* and *Revista de Administração Pública*.

In most of the articles, the authors conceptualized healthcare regulation by using more than one of the typological ideas elaborated, in different passages within the article, and from a variety of combinations of these ideas. Nevertheless, in four articles, no definition for regulation was identified.

There was no relationship between the ideas contained in the regulatory concepts and the year in which the articles were published, but there was a relationship with the topic that the articles dealt with. The topic that was covered most, in the majority of these articles, was the public/private combination, followed by the relationship between the Brazilian national healthcare system (*Sistema Único de Saúde*, SUS) and the supplementary market system.

Combinations of the ideas of control and direction were the types of combination most frequently identified in the definitions of regulation in the same article. The idea of control was always present when regulation was conceptualized with one of the four fundamental typological ideas of regulation. Conceptualization of regulation from this idea was frequently based on understanding regulation as a function of the state, especially a legislative function.

Regulation was also envisaged as an activity that required scientific and technological knowledge in order to implement it, such that this knowledge would be a prerequisite.

The idea of balance was strongly associated with discussion of the topic of the public/private mixture. A regulatory concept relating to improvement of market efficiency that was implicit in this notion of market failure was observed. Thus, in a certain way, the state's role was seen to be complementary to the market action, thereby ensuring its viability.

The idea of adaptation was little used in the definitions of regulation used in the articles selected. Even so, it could be grasped that through using this idea, regulation was conceived as an activity of achieving compatibility with the existing norms and rules. This also revealed that the regulatory activity would not consist only of applying norms and rules: the regulatory action in itself would be a means of influencing change, thereby updating these norms and rules.

In the articles that used the idea of direction, regulation was associated with the activity of planning and formulating public policies. This idea would make it possible to identify the political dimension of regulation. It would consist of taking the conception of regulation beyond the notion of correction and control. As a public policy (political, social and/or economic), regulation would represent a way of commanding or governing. From this idea, the way of conceiving of regulation is directly influenced by the governance model adopted.

The healthcare regulatory concepts used by these different authors have in common an understanding of regulation starting from the logic of state intervention, either directly or indirectly. Thus, regulation is presented as a state activity connected with a variety of functions: normative, administrative, economic, political and governance-related. However, what differentiates these concepts is the different forms of state intervention.

FINAL REMARKS

The four fundamental ideas for conceptualizing regulation made it possible to produce a synthesis of this conceptual polysemy and essentially distinguish two natures for regulation. The ideas of control and balance corresponded more to the technical component, whereas direction and adaptation referred to the political component of regulation.

The way in which healthcare regulatory concepts have been used in the Brazilian healthcare system is not uniform and, in fact, this reveals the configuration of this system. It is possible to distinguish at least two conceptual groups. The first relates to understanding regulation from the actions of the public subsystem. Here, regulation is understood both as controlling users' access to healthcare services and as an act of regulating and drawing up rules. The second group of concepts relates to the private subsystem, such that regulation is envisaged as correction of healthcare market failures.

Regulation was linked to a wide range of distinct actions: rule-making, inspection, control, auditing and assessment. However, a normative and bureaucratic emphasis towards this form of conceptualizing regulation was observed, generally expressed as the act of complying with rules.

The reforms produced significant redefinition of the control mechanisms and political nature of regulatory action. This resulted mostly from redefinition of the functions of the state itself, given that the new prominence of market mechanisms implied changes to the social protection structures.

The traditional regulatory models were shown to be insufficient in the light of the current challenges of these systems. However, no situation of complete dismantling

of all state regulation was seen. Rather, there was a new regulatory project: new regulations linked to the changes in the manner of governance.

As pointed out by several authors,^{11,16,17,19} the increasingly common tendency towards delegating the functions or attributions of the state to the private sector is one of the important causes of growth in the state's regulatory function. The aspects of this trend include: transfer of responsibilities to private entities, outsourcing and new competitive and contractual arrangements within healthcare systems.

Thus, regulation has progressively ceased to be seen only as a separate control activity over the private sector, to become a new systematized form of state action.¹⁹ The boundary between state and market is what delimits the function and action of regulation.

From this perspective, regulation has become a premise for modernization and increased efficiency of public service provision, and has gained new importance and significance as a result of this process of reformulation of the state's role.

Among the published papers selected, the healthcare regulatory concepts were perceived as having greater emphasis on regulation of a more technical nature. The political nature of regulation remained secondary. One possible explanation for this phenomenon was greater interest in the discussion on regulation consequent to the debates around the issue of state reform.¹⁴

The introduction of new types of management for SUS, such as social healthcare organizations and state foundations constituted under private law, have given rise to new challenges for the capacity of state regulation, with regard to ensuring universal egalitarian access to healthcare services and actions for the population.

Comprehension of the public/private relationship in the Brazilian healthcare system is a fundamental issue for the discussion on healthcare regulation, like the early privatization process in the Brazilian healthcare system.¹⁸ This has caused structuring of healthcare service production in a private profitmaking manner.¹⁰ Thus, the issue of regulation within the Brazilian healthcare system needs to be thought about from the perspective of this strongly privatized structure.

REFERENCES

1. Baldwin R, Cave M. Understanding regulation: theory, strategy and practice. New York: Oxford University Press; 1999.
2. Boyer R, Saillard Y. Théorie de la régulation: l'état des savoirs. Paris: La Découverte; 2002.
3. Bruno M. Macroanálise, regulação e o método: uma alternativa ao holismo e ao individualismo metodológicos para uma macroeconomia histórica e institucionalista. *Rev Econ Polit.* 2005;25(4):337-56. DOI: 10.1590/S0101-31572005000400002
4. Canguilhem G. A formação do conceito de regulação biológica nos séculos XVIII e XIX. In: Canguilhem G. Ideologia e racionalidade nas ciências da vida. Lisboa: Edições 70; 1977. p. 73-89.
5. Castro JD. Regulação em saúde: análise de conceitos fundamentais. *Sociologias.* 2002;4(7):122-35.
6. Chevallier J. De quelques usages du concept de régulation. In: Miaille M. La régulation entre droit et politique. Paris: L'Harmattan; 1995.
7. Chinitz D. Good and Bad health sector regulation: an overview of the public policy dilemmas. In: Saltman RB, Busse R, Mossialos E. European observatory on health care systems: regulating entrepreneurial behavior in european health care systems. Philadelphia: Open University Press; 2002.
8. Di Pietro MSZ. Direito Regulatório: temas polêmicos. Belo Horizonte: Fórum; 2004.
9. Elias PEM. Estado e saúde: desafios do Brasil contemporâneo. *Sao Paulo Perspec.* 2004;18(3):41-6. DOI: 10.1590/S0102-88392004000300005
10. Gazier F, Cannac Y. Étude sur les autorités administratives indépendantes: études et documents. Paris: Consul d'Etat; 1984. (Etudes et Documents du Conseil d'Etat, 35).
11. Kumaranayake L. The role of regulation: influencing private sector activity within health sector reform. *J Int Dev.* 1997;9(4):641-9. DOI: 10.1002/(SICI)1099-1328(199706)9:4<641::AID-JID473>3.0.CO;2-8
12. Lauwe PHC. Régulation et transformation sociale. In: Gadoffre G, Lichnerowicz A, Perroux F. L'idée de régulation dans les sciences. Paris: Maloine-Doin; 1977. p.49-58.
13. Majone G, Baak P. Regulating Europe. Londres: Routledge; 1996.
14. Miaille M. La régulation entre droit et politique. Paris, L'Harmattan; 1995.
15. Prévost P. La régulation biologique: un concept intégrateur de la connaissance agronomique. Éditions INRA. 2000 ; 39 :27-38.
16. Saltman RB, Busse R. Balancing regulation and entrepreneurialism in Europe's health sector. In: Saltman RB, Busse R, Mossialos E. European observatory on health care systems: regulating entrepreneurial behavior in european health care systems. Philadelphia: Open University Press; 2002. p. 3-52.
17. Santos IS, Ugá MAD, Porto SM. O mix público-privado no sistema de saúde brasileiro: financiamento, oferta e utilização de serviços de saúde. *Cienc Saude Coletiva.* 2008;15(5):1431-40. DOI : 10.1590/S1413-81232008000500009
18. Schneeberger P. La place des modèles dans l'enseignement du concept de régulation. In: Rumelhard G. La régulation en biologie – Approche didactique: representation, conceptualization, modélisation. Paris: Institut National de Recherche Pédagogique; 1994. p. 131-64.
19. Viana ALDA, Elias PEM. Saúde e desenvolvimento. *Cienc Saude Coletiva.* 2007; 12(Suppl.0):1765-77. DOI: 10.1590/S1413-81232007000700002

Article based on the master's dissertation of Oliveira RR, presented to the School of Medicine of the Universidade de São Paulo in 2010.

The authors declare no conflicts of interests.