Public regulation of the health care system in Brazil - A review*

Fausto Pereira dos Santos^{I,**}; Emerson Elias Merhy^{II}

^IDiretor Presidente, Agência Nacional de Saúde Suplementar, Rio de Janeiro, RJ. <faustops@ans.gov.br>
^{II}Professor visitante, Pós-Graduação da Clínica Médica, Universidade Federal do Rio de Janeiro; professor voluntário, Departamento de Medicina Preventiva e Social, Faculdade de Ciências Médicas, Universidade Estadual de Campinas. <emerson.merhy@gmail.com>

ABSTRACT

Aiming at analyzing the public regulation of the health care system in Brazil, this essay concerns the area of Healthcare Management and Policies. Taking regulation to mean the capacity to intervene in the offer of services, changing or orienting their execution, the paper discusses its historical evolution, its determinants, the different regulation strategies used, their objectives, the actors involved, and, in particular, the instruments created by the government, one of the actors. The study is based on a review of the subject, debating conceptual issues and the tools used in the regulatory process in the healthcare field, its reach and limitations.

Key words: health policy. SUS (BR). health planning. health service.

Introduction

The classical economic theory describes the law of supply and demand as the determination of the price and quantity of goods sold in a competitive free market. When the conditions for a competitive market are not met, the market will fail and outcomes will not be efficient. The health care market is organized in a way that it fails to meet the requirements for a perfectly competitive market in many different ways. When market failure occurs, state intervention in the economy should take place. (Castro, 2002; Donaldson & Gerard, 1993; McGuire et al., 1992).

Donaldson & Gerard (1993) identify the following characteristics of perfect competition: rationality, inexistence 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. This would justify state intervention.

The main identified market failures are: risks and uncertainty; moral hazard; externalities; information asymmetries; and the existence of barriers. (Castro, 2002).

1

In economic theory, regulation could be characterized as a state intervention in order to correct market failures using mechanisms such as financial incentives as well as control and command incentives. Regulation as a category is largely used in public administration, social sciences and economics. According to Boyer (1990, p.181) that would be a conjunction of mechanisms that would make the reproduction of the whole system possible, based on the conditions of economic structures and social forms. In the health sector, this term, besides referring to the macro processes of regulation, also defines the mechanisms used to direct and shape health care itself (Andreazzi, 2004).

The action of regulating in health care is part of the field of rendering services, being carried out by the various actors or institutions that provide or hire health services. The concept, practices and purposes of health regulation are still under discussion and there are different understandings of the issue, besides being subject to changes over the years and to the understanding of social actors.

As Magalhães Jr. (2006, p.40) presents the issue:

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.

D'Intignano & Ulman (2001) mentioned by Magalhães Jr. (2006) analyze regulatory politics from the point of view that health politics aim to find equilibrium among three main objectives: 1) macroeconomic reality, which imposes that expenditures must be paid by revenue, and besides imposing a system that do not hamper production and employment; 2) microeconomic efficiency, which demands a satisfactory level of services rendered as well as a system with good performance, productivity and no waste; 3) social equity, which must be translated into access to medical care and into an equitable geographic share of resources.

Regulation in the Brazilian Health System

The importance of health regulation in Brazil is attributed to the model adopted over the years to render health services. he regulation process is here understood as the intervention of a third party in issues involving consumers' demands and effective rendering of health care services. Regulation was already present back in 1923 in the "Caixas de Aposentadorias e Pensões – CAPs" ¹ and also in the "Institutos de Aposentadorias e Pensões –IAPs", as rules for the utilization of health services and drugs were established, as well as those for providing beneficiaries with health care. When it comes to the IAPs, as the adopted model was about buying health services from health professionals instead of having them directly rendered by the IAPs, these actions of intervention were intensified. All of them were characterized as health care regulation.

_

¹ Caixas de Aposentadorias e Pensões - private organizations of health benefits for some professional categories.

With the foundation of the National Institute of Social Security -INPS (Instituto Nacional de Previdência Social)² in 1966, this process became faster and health care services provided by the state started to occur basically through the acquisition of private health services. As INPS needed a great number of health professionals spread out all over the country, the process of forming this network could be characterized as the first and most important regulatory mechanism used by the National Institute of Social Security. The criteria used, as well as the profile of the accredited network, initially defined the health care guidelines to be used from that time on. Therefore, this model adopted a way of regulation, which involved all of its providers, in a variety of formats: commercial regulation, administrative regulation, financial regulation and assistance regulation. Commercial and payment relation with the accredited network of health professionals defined health care standards and relation. After opting for paying for procedures through Service Units, all the network of providers were directed to some logic of production of more expensive and isolated procedures. The administrative operation originated from this commercial format could be another regulatory aspect defining health care. Those mechanisms of evaluation and control previously defined began to strongly induce the type of health care provided by the accredited network. Administrative reviews, disallowances, and authorizations defined what could be done and what could not be done and standardized the way providers could operate in the health care system. Another important aspect was the financial regulation, which occurred basically through budget restrictions and value definitions according to a remuneration table. Payment capacity and value increase of procedures, or its absence, defined which procedures would be carried out and to which extent, besides defining the type of access beneficiaries of the system would have.

At this initial moment, assistance regulation was considered the least important aspect in the elaboration and consolidation of a regulatory milestone in health care in Brazil. The mechanisms initially established have a narrow relation with the qualitative aspects of health care services, access regulation, and eligibility criteria for the provision of health care.

It is important to emphasize that this process was intensified with the expansion of private health care services hired by the National Institute of Health Care (INAMPS) in 1978. This Institute worked together with private providers hired by the Brazilian Social Security System, trying to control especially the production and expenditures in health care. This kind of regulation model focused on the control of expenditures of the sector, supported by an excessive number of norms, imposition of rules and flows. In the case of INAMPS, the bigger was the financial crisis of the institution, the more intense was the regulatory process. An example of this kind of restrictive practice was the administrative ruling no. 3.042/1982, which limited the number of medical exams according to the percentage of consultations with the objective of controlling the provision of services (Brazil, 1982). INAMPS' evaluation and control system developed proportionally to the increase in demands for health care and especially to the number of health care providers. This model of regulation was characterized by its high level of centralization, vertical actions, and

_

² Instituto Nacional de Previdência Social –INPS was created in 1966 to unify all health benefit organizations.

central decisions and by the duality coming from different institutional and leadership cultures, which is expressed by the fragmentation of state actions towards health promotion. In general, this situation is evidenced, on the one hand, by the normative planning methods used, as well as parametric administration and control, and financial evaluation methods. On the other hand, it is evidenced by organizational methods of services and evaluation based on public health vertical programs (Merhy, 1992).

An important step in the regulatory process was the development, at INAMPS, of the traditional systems of control, evaluation and auditing. In the decentralization process to State and Municipal Departments for Health Care, these services were incorporated with the same logic of their original constitution. Actions developed occurred in a quite normal way and had as an objective the follow-up of the economic relations established with the accredited providers, especially those related to the correction of the bills presented.

This paper aims at discussing the Public Regulation of the Health Care System in Brazil — following the implementation of SUS (Unified Health System) — in its multiple aspects: concepts, history, its determinants, the process of formulation, regulatory strategies, the actors participating in the process of regulation, and particularly the instruments created by the government to facilitate the regulatory process.

The distinction among different concepts

Regulation can be understood as the capacity of intervention in the processes of service provision, making arrangements to or giving instructions for their provision. This intervention can occur through a variety of mechanisms: mechanisms that can induce some kind of action, mechanisms that stabilize mechanisms that regulate or mechanisms that limit or restrict actions. The intervention in issues involving demand and direct provision of health care services, in their several aspects, can be characterized as a regulatory mechanism. Demand, as well as health care services, can be organized in many different ways and be related to a wide range of fields. Therefore, the possibilities of intervention, that is, regulation, are also extremely diverse.

The first distinction to be made is that between the terms *regulation* (regulação) — in the sense of state intervention in imperfect markets when market failure occurs (Market failure is a term used in economics to describe a situation in which markets do not efficiently allocate goods and services) — and *regulation* (regulamentação) as the act of regulating a principle or a rule. Regulation — in the first sense — is here understood as a main concept, which expresses the actor intention in using his capacity, his conferred power. Regulation — in the second sense — can be understood as the act of putting under a system of rules or norms in order to guarantee this intention. Thus, this process of law regulation will be subordinate to the main process of regulation.

Both terms have not been used in a very strict way, although law regulation has been used in the sense of a process of production of acts supposed to regulate, followed by a political and administrative process of regulation of contractual aspects and relations among actors with conflicts of interest.

We also observe that the regulatory process occur both in people's everyday access to health care services (micro-regulation) and in the aspect of defining the most general policies of institutions, which has been called macro-regulation. Macro-regulation consists of strategic mechanisms of management: the establishment of strategic plans, priority projects, and projects related to social control, budgetary definitions and to other social policies which interfere in the improvement or not of the health of a population, the policy of human resources and the establishment of rules for relations with the private health sector, which is always an important actor.

The regulatory process is placed into a scenario of disputes and conflicts of interest which determine its format and its scope. Macro-regulation can be established on social political bases, as the one supported by the Brazilian Sanitary Reform (reforma sanitária) and foreseen in the legal provisions of SUS³; on corporate or technocratic bases and/or based on the interests of private markets. We can affirm that there is no system without regulation. The difference is established on the premises and disputes that guide the current regulation. In this sense, we can have a model that stimulates and expands the private sector as the one conducted at the time of IAPs, INPS and INAMPS, or a model based on public support (patronage), as the one recommended by the Sanitary Reform and the legislation that institutionalized it - Brazilian Constitution and Health Organic Law (Brazil, 1990a; 1988; Oliveira & Teixeira, 1986).

Micro-regulation or health care regulation translates the everyday operation of the system, the general rules established in macro-regulation. It consists in articulating and gathering the potential responses of the system for the dynamic demands of a population, providing access to health services. Besides, it implies the evaluation of what has already been planed in the different aspects of health care that is, providing management with an operational regulatory intelligence. In a system which is regulated in terms of assistance, the consumer, when entering the service network, starts being directed by the system. (Magalhães, 2002).

It is important to emphasize that, although regulation has a number of the attributes which characterize the management process, it is just a part of this process, not the whole of it. This controversy made it difficult to institutionalize the discussion in the scope of the SUS´ managers, for it could suggest the substitution of management and managers for regulators, especially in terms of assistance regulation.

Other important definitions, which were the central part of the instruments developed by the extinct INAMPS, are:

a) The concept of control, which can be understood as the permanent process of monitoring the performance of an action, in accordance with what was prescribed, analyzing if what is being done is close to a standard, to a previously set limit, or if distortions are occurring. Control can be established after, at the same time or in advance of the process being monitored.

-

³ SUS- Unified Health System

- b) The concept of evaluation, which can be understood as a process of systemic and objective determination of the relevance, effectiveness, efficiency and impact of activities based on their objectives. It is an organizational process used to implement activities and to help in the processes of decision-making, planning, and programming. It also consists of a way of learning through experience, leading to better planning (OMS, 1989). Contandriopoulos et al. (1997, p.31) emphasize that evaluation consists basically in making a value judgment about an intervention or any of its components with the objective of helping in the decision-making process. Thus, evaluation can be considered a tool linked to the processes of decision-making, planning and management. It is supposed to help to improve performance, review and redirect actions.
- c) Auditing is a group of techniques used to evaluate processes and results as well as the utilization of financial resources through the analysis of a situation compared with some specific technical, operational and legal criteria. The purpose of auditing is to confirm the legal and genuine aspects of acts and facts and evaluate the results obtained in terms of efficiency, and effectiveness of budgetary, financial, operational, finalistic, accounting, and equity management of units or systems (Brazil, 2001).

It is important to emphasize that the group of activities developed did not consolidate these concepts in health-care daily activities.

The actors in the regulatory system

In this context of disputes, it is important to understand who the implicated actors are and which interests in the scenario define the presuppositions and mechanisms required in the regulation process. We find support in Matus (1987, p.754), who defines social actor as a personality, an organization or a human group, which has the capacity to accumulate strength, develops interests and necessities and act producing facts in the whole context, either in a stable or transitory way. As presented by Cecílio (2004), the concept of Matus about social actor is approximated to the social strength concept, that is, movements that represent and organize a portion of the population that go around common objectives. What characterizes and makes different a social strength from a social group, social level or a disorganized crowd is its constitution as a stable organization, with permanent capacity of accumulating strength and events production by the application of this strength (Merhy et al., 2004; Campos, 1992).

With the comprehension that social actor, in a historical context, seeks to regulate health services according to the interests of the group he represents, that is, tries to direct health production to its macro objectives. The interests and disputes among social actors are done in a specific historical and political context. The regulated actors behave in different way to this regulation.

In the IAPs context, health services were bought instead of being rendered by the institute and regulation was conducted based on this way of providing services. This model remained the same in the following decades, since regulator actors were confused with regulated entities. The sanitary reform, a political movement to

reconstruct the Brazilian Health System, understood health as a human right and a state obligation, and made possible the construction of a new political actor, or a new symbolic identity.

The struggle to democratize health involved professionals and intellectuals of health sector and an organized social movement. All the movement about the anti-hegemonic project, since 1970, merged to the VII National Health Conference, in 1986, that was consubstantiate afterwards, in 1988, with the constitution and Organic Law, which gave the juridical support to the project and listed new principles and guide lines to the public regulation (Malta, 2001; Paim, 1997; Brazil, 1988).

These have not meant that the regulatory process introduced by the Brazilian government had suffered a significant change in direction, and that the new presuppositions became the central issue. The interests of the regulated actors and the regulators dynamic remained permanent up to nowadays, in a smaller or bigger importance, in the regulatory process that is happening.

The regulation in the legislation

With the legislation that followed the Constitutional process, issues like control, evaluation, auditing and regulation came up to discussion. Article 197 of the 1988 Brazilian Constitution presents:" The health services and actions are publicly relevant and it is the responsibility of the government to legislate about its regulation, inspection and control, and its execution must be done directly or throughout third parties and also by individuals or juridical person. "(Brazil, 1988).

Law n° 8.080 defines the competency of each government level and establishes the National Auditing System (Brazil, 1990a).

The process of regulating the relation among federal entities was enforced by the publication of the operational norms (NOB 01/91; NOB 01/92; NOB 01/93; NOB 01/96 and NOAS 01/2002). Expressed at greater detail or not, all norms talked about the regulation process and all its components, especially control and evaluation. The principal attempt was always to define the role of each government level in the regulatory process.

In the Norm 01/91 public and private providers were attributed the same level and the same distribution mechanism of financial resources were used for both of them, establishing that the distribution of INAMPS budget resources to states and counties to pay hospital and outpatient care would be done by grants and by production, besides determining criteria to monitor, control and evaluate the actions covered by this financial mechanism. Thus, the first big normative act already had exposed that the regulatory mechanism used at the first moment would not be discontinued; on the contrary, it would be expanded to public sector. It was assigned to INAMPS the control and supervision of the financial execution (Lecovitz, 2001: Brazil, 1991). Norm 01/92 defined competencies and according to them, counties were responsible for the control and evaluation of the assistance services and states were responsible for the periodical evaluation of the services and for the municipal monitoring. Norm 01/92 made the generic recommendation that evaluation should

verify services efficiency, efficacy and effectiveness, the fulfillment of goals and results. The Federal

government would analyze and pedagogically correct the development of health care control and evaluation in the National Health System with counties and states technical cooperation. It was also established in this norm that the control and supervision of the financial execution was going to continue to be done by INAMPS, as declared previously in norm 01/91. The Outpatient Information System and the Hospitalization Information System were also formatted. The Hospitalization system arrangement in fact, systematized what was being done with the hospitalization authorizations (Brazil, 1992).

In this initial period of SUS implantation, the effective control and evaluation actions were centralized at INAMPS and/or at the decentralized state units, with a small participation of the counties, that were restrict to inform quantitative data about hospital and outpatient production. In the states, the daily flows and routines were basically the same defined previously by INAMPS.

Norm 01/93 presupposed different modalities of administration by the counties and states and after its edition the automatic transference of financial resources launched, originally foresaw by the legislator at the time of Law 8.080 edition (Brazil, 1990a). The mechanism to transfer financial resources directly from federal government to state/municipal government was regulated by decree 1.232/94. From that time on, a part of the management process, including the regulatory capacity was transferred to state and municipal administration. To be able to administrate the resources totally or partially, the states and counties had to prove, among a variety of requisites, the constitution of the control, evaluation and auditing services, with physicians designated to sign the hospitalization authorization and high cost outpatient procedures, technical capacity to operate the outpatient information system, the hospitalization information system and the central control of hospital beds (Brazil, 1993a).

With the edition of norm 01/93, around 140 counties turned to the condition of local managers, receiving the whole financial resource to do all health actions, including the private regulation. In this context, SUS' managers took as their mission the development and improvement of management tools, aiming to organize the control, regulation and evaluation functions.

Another impulse in the decentralization of the regulatory process was the INAMPS extinction in 1993 and the creation of the National Auditing System, regulated by law in 1995 (Brazil, 1995). The principal activities of the National Auditing system were the control of actions according to established standards; evaluation of the structure, process and results; auditing the services regularity by analytical and skill examination as well as the control of the consortiums among counties.

Norm 01/96 was about the specific requisites for states and counties habilitation in the system management. Norm 01/96 implanted new ways of financing actions as: a specified minimum amount of resource for primary health care, incentives for community health agent programs, Family health program, among many others (Brazil, 1996). All resources began to be transferred directly from federal government to counties and states, according to the fulfillment of the prerequisites for habilitation. This way, gradually, part of the resources was not linked to procedures production anymore and began to be directly transferred according to the population proportion number and/ or to the historical series. The creation, in 1999, of the Strategic and Compensation actions resources, under federal administration, to pay for specific Health Ministry projects, besides some high complexity actions, meant an interruption in the decentralization process, which had

began with the edition of norm 01/93 and maintained in the federal level a variety of regulatory mechanisms, to high complexity services or to strategic actions. The resources from Strategic and Compensation actions resources began to be transferred directly from federal to state government, and were linked to the provider's payment, or the federal government would make the payment, as when transplants surgeries were done. Truly, this meant a new centralization of the federal government regulatory capacity and put again in the scenario the actors that, in the process that were going on, had loosened a big portion of their intervention capacity.

The most important improvement in the 1996 norm consisted in the inclusion of more than four thousand counties in one of the administrative level (primary health care or information system), bringing the discussion about regulation to the counties.

Another important measure in the regulatory process was the edition of the Health Assistance Operational Norm – NOAS 01/2002, that aimed to regionalize health care services, transferring to states the competency to organize flows of health care services among counties. NOAS defined mechanisms to reorganize reference flows and introduced the health care regulation concept, or the access regulation to urgencies, consultations, etc. It also established SUS manager's control and evaluation functions; quality evaluation of services produced; beneficiary satisfaction; results and impact in the population health, as well as the elaboration by states and counties of Control, Regulation and Evaluation Projects (Brazil, 2002a). The difficulties to have this norm implemented were related to its postulates and proposals. NOAS and its related rules tried to enclose the many different situations with a frame, presupposing a strong regulatory action in the states and ended up restraining the decentralization process in the municipal level. Besides, the regulatory proposal was restricted to high and medium complexity procedures, maintaining it separated from control, regulation, evaluation and auditing actions. It also presupposed regulation as a specific activity, limiting its potential of intervention and separating it from the control and evaluation actions.

The state regulatory action created new instruments at the end of 1990: i) regulation of private health insurance (Law 9.656/1998); creation of the Brazilian National Private Insurance Regulatory Agency - ANS (Law 9.961/2000); and the creation of Brazilian National Sanitary Agency (Brazil, 1999). ANS was created as an institution to regulate, control and supervise the private health insurance activities (Brazil, 1998; Brazil, 2000). It is important to emphasize that there are more than 40 million beneficiaries in the private health insurance market.

The principal instruments of public regulation

We will analyze with more details the instruments that made possible SUS' public regulation, its possibilities, improvements and limits. Among the instruments and mechanisms used in the regulatory process, we can emphasize: financial area, definition of the network providers, contracts for health services, registration of the health care services units, health care programs, Hospitalizations authorizations and authorizations for high complexity procedures, national data base, central information system about hospital beds, analytical and operational auditing, monitoring of the health public budget, evaluation and monitoring of health care actions, among others.

We emphasize that the principal mechanism that inducts health actions and services is the resources allocation, through its most visible instrument, the authorized medical procedures list. This way of performing has been utilized by federal government during a long time, as the principal mechanism of induction of health services provision. Since the beginning, with INAMPS, the authorized procedures list has been used as instrument to pay the providers and health services administrative body. Its capacity of induction occurs either by a list of procedures to be executed as by its previously defined prices.

The definition of network providers - according to Brazilian Constitution - can be public, complemented by private providers, have a high regulatory power about the health care service rendered. The Brazilian health System, historically, at the priority moment of a majority private network, defined a standard of a commercial relation in the health care conformation. The conformation of this network was done, initially, by credential mechanisms, adopting criteria not well explained, strongly influenced by political and economical interests (Oliveira & Teixeira, 1986). This relation have its roots in the history of Brazilian Social health, persisting, still, in the SUS, contract traces of the extinct INAMPS, or even in the poor situations, without formalization, although existence of legal requirements. After 1988 Constitution and the definition of SUS, besides the complementary characteristic of the private sector, the necessity of the bid process to contract services was imposed.

The health services contracts are another instrument that contributed to the development of the manager regulation, once there are clear rules forecast to obligations and duties among each part in the signed contracts, including the subordination of the contracted services to the administrator regulation. The necessity and the general guide lines to contract health services is given by the 1988 Constitution: "The private institutions can participate of the Public Health System, according to its guide lines, with a contract of public law or a contract, having preference the entities without lucrative means (Brazil, 1988).

In a effort to contract health services providers, in October of 1993, the Ministry of Health edited norm n. 1.286/93, which establishes standards to firm contracts by the local and county administrators, its network providers (Brazil, 1993b). However, this process has been developed in a extremely slow and unequal way by states and counties. In 2003, the trying to reorient and accelerate Ministry of Health launched a new document trying to reorient and accelerate (Agreement Manual) seeking to reorient and accelerate this process. In the process, it is anticipated that the public interest and the identification of health care necessities should orient the process of buying health care service in private network, which must follow the legislation, the specific administrative norms ad the flows of approval, when the avaiability of public network is insufficient to care for the population, defined in the special commissions that have the participation of all state and county administrators (these commissions are forums of discussion and agreements, in each state, composed by a representative of the county secretariat of health and the state secretariat of health). This process must be followed by the monitoring of the invoicing(billing), quantity and quality of services rendered (Brazil, 2003). The contracts should be a necessary instrument to control and qualification of care.

The official register of units that render health services(CNES)- completed and actualized- is a basic requisite to program the contracts of health care services and to control the regularity of the bills. The constant actualizations of CNES of each area to be regulated are essential instruments to health care regulation. CNES can and should be gradually more used by the others informational subsystems as an updated data base, inclusive to the private sector regulation, once the Brazilian National Regulatory Agency has been demanding the registration of all private health units within CNES as a prerequisite to register in the Agency. With this, the system will have updated registers of health units and that will make possible the administration and regulation of the public sector that have contracts with the private sector and, more recently, the private sector.

The care program that is reflected in the budget index of the health units is another instrument utilized to adequate the services offer with the consumer necessities.

The national data bases are essential instruments for the control, evaluation and auditing functions. To feed the data base in a permanent and regular way is fundamental to its improvement, as well as to its utilization in the monitoring and evaluation process of the system. There are many different information subsystems that can be used in this process. Among them we can give emphasis to: Outpatient Information System; Hospitalization Information System; Mortality Information System. All of them have a distinct origin, design, data base and finality and all this turn their integration and articulation difficult.

The Hospitalization Information System was implanted in 1976, to administrative objectives and to verify health care provider's costs and payments. In 1983 the Hospitalization form was implanted and gradually amplified to hospitals. In 1999, the Ministry of Health assumed the system administration, extending to all hospitals units and, in 1994, the system was decentralized to States and Counties Health Secretariats and them it was possible to analyze and obtain reports in anyone of the system levels. The SUS Hospitalization Information System collects data about: hospitalization, patient characteristics, time, place, patient origin, services characteristics, procedures done, deaths, amount paid, International disease Codification. There are many limits to the use of the information, among them we can list: i) the fact that Hospitalization authorization is a instrument to facilitate health services payments and it can be distorted, fraud and over billed; ii) lack of standard training to classify diseases; iii) variations in the technological characteristics of the network; iv) the fact that is not universal representing around 80% of the hospitalizations in the country (Carvalho, 1997). Therefore, even with its limits, the Hospitalization Information System is an important source of hospital morbidity in the country, health situation, monitoring of tendencies and evaluation of health action and services results. Its systematic utilization can serve as stimulation to qualitative and quantitative improvement of its own data.

The Outpatient Information System was implanted in 1991 and follows the same logic as the Hospitalization Information System, specially related to amount paid and health services providers' payment. The unit used to register in the system is the outpatient procedure done, separated in each professional activity

(consultation, lab procedures, etc.). There are no data about diagnose and reasons for the necessity of care, which is an obstacle to verify the morbidity profile, except infer about access, consumption and utilization of services; it does not reveal, still, patient origin, flux. In 1997, a great improvement occurred with the introduction of the High complexity procedures authorization subsystem (kidney substitutive therapy, oncology, burns, nuclear medicine, exceptional medications, and prosthesis among others, what increased the control over these procedures.

Another important regulation instrument consists in the central units equipped with information systems about number of available Hospital beds, consultation, diagnose and tool, the Regulatory system, that proposes to integrate the many different regulatory central units and this can therapeutic services, urgencies and ambulance service. There are states and counties that took the initiative to develop this central units. The Ministry of Health developed a be an important instrument to regulate access to care.

The development of the health care regulatory process will be done in consequence of an integration of this and the others subsystems and a National Health information System, articulated, with the same information standards, tables, official registers—data entry, common identification, that make linkage possible, pull out indicators and can constitute, in fact, an instrument to the actions of regulation and evaluation of health care.

The analytical and operational auditing actions are responsibility of the three governmental levels of SUS. Auditing must analyze the developed activities, proposing correctives measures, interacting with other administrative areas.

Others control and evaluation mechanisms should be adopted by the public administrator, as: monitoring of Health public budget, coherence analyses among program production and bills presented and implementation of critics made possible by the informative systems related to information consistency and confidence made available by providers.

The implementation of an evaluation process of health care actions, in a systemic and continue way, about structures, processes and results permits a better planning, adjusts in the execution and seek for improvement, efficiency, efficacy and effectiveness. The health care quality evaluation, by the administrators, must involve either the implementation of objectives indicators as the technical criteria related to the adoption of instruments to evaluate the consumer satisfaction, which consider the integral access of care, resolubility and quality of rendered services, constructing mechanisms that can guarantee the participation of population in the system evaluation. The dimensions contemplated: evaluation of the system organization and administration model; evaluation of the service providers relation – the public administrator must have instruments that permit monitor the providers in the execution of programmed resources; evaluation of quality and satisfaction of system users; evaluation of results and effectiveness of action e services according to the population epidemiological standards – should involve the monitoring of results reached because of the objectives, indicators and goals pointed out in the governmental health projects.

The control, regulation and evaluation functions impose to administrators the superation of methods that refer themselves mostly to the control of bill and instruments of evaluation with structural aspect and the process, over valorized compared to aspects of evaluation of results and of the consumer satisfaction (Brazil, 2002b).

There are, still instruments to guide administrators actions and to supervise and supervise the implementation of the sector politics by the Health Council and formal instances of control, regulation, evaluation, as: Health Strategic Planning, approved by the Health Council; The Investments and Regionalization Director Planning; Integral and pact Program; Primary Health care Pact; Guarantee Terms of Access and Compromise among public sectors; etc. (Brazil, 2002a).

Conclusion

There are many different challenges in the implementation of public regulation, among them, its finality, or who would be the beneficiary of this action. The presupposition of public regulation not always commands and defines the action. Many times, the state finds itself dependable of others dispute of interests and defines regulation and its mechanisms anchored in these presuppositions.

It is important to emphasize the exclusive and articulated command of SUS in the three government levels. Only this three government level integration can guarantee the right direction and conduction of SUS with the standards politically defined in the Brazilian Constitution. However, this articulation and partnership are in process of construction, and have been permeated by disputes, many times because of different interests. Thus, the Commissions that represent counties and states function as instances of harmonization, publicity and agreement of all interests.

A notable SUS innovation consisted in the unified command in the three level of government. This implies in the assumption of the three governments level of their prerogatives and responsibilities in the public regulation, making the integration between the public and private sector which render health services with the public sector. It is important to emphasize that this perspective has not been an easy task. The system management is a gradual process, assuming the actions of control and evaluation of the private health services contracted by SUS.

It is an attribution of the Municipal Health Departments the challenge of assuming the system management, advancing to its real integration, assuming the planning of actions, establishing the adequate availability of services according to the identified necessities. At the same time regulation guarantees the access to health services to the individuals, it also acts to guarantee the availability of services, subsidizing the control of the services provided, to expand or reallocate the programmed offer and this way accomplish its mission. Regulation promotes, this way, equal access, guaranteeing the integrality of health care and permitting adjustments in the assistance available to the immediate necessities of the citizens, in an equal and ordered way.

Another fundamental aspect consists in the inter relation between the assistance model and the regulation established. Regulation has its own dynamic and logic turned to control of actions, have a tendency to be separated, restricting itself to control private health sector action and becoming isolated from the group of assistance actions and from its own services. This duality can be overcome by integrating the necessities, demands, flows, having the beneficiary as a reference to organize services.

Some of the initiatives are still incomplete, as, for example, the services network provider contract. This services network, subrogated by the extinct INAMPS to the States Health Department, was also subrogated to the Municipals Health Departments, the majority of it with expired or null contracts, rendering services just based on "special contracts", without defined criteria. Many counties had already started to adjust the contracts and solve the problems, but there is still a lot to be done. Important regulatory instruments, as the Regulation Centers, are articulated with the Urgency Centers, but are punctual and isolated initiatives and can not be constituted, up to now, in a systemic way.

Another important action consists in the integration of the data base subsystems to compose an articulated and integrated National data base system that makes regulation and evaluation possible.

Finally, the last challenge is the system evaluation, which is a fundamental part in planning and management of the health system. An effective evaluation system can reorganize the health and services actions, redefining them in order to contemplate the population necessities and using the resources in a rational way. However, evaluation is not frequently done. There are many reasons for this, from the lack of financial resources to methodological difficulties, human resources insufficiency and, some times, absence of political wish to talk about this issue (Malta, 2004).

References

ANDREAZZI, M. F.S. Mercado de Saúde Suplementar: amplitudes e limites na arena da regulação. In: MONTONE, J.; WERNECK, A. (Org.) **Documentos técnicos de apoio ao Fórum de Saúde Suplementar de 2003.** Rio de Janeiro: Ministério da Saúde, Agência Nacional de Saúde Suplementar, 2004. p.121-46.

BOYER, R. A teoria da regulação: uma análise crítica. São Paulo: Nobel, 1990.

BRASIL. Ministério da Previdência e Assistência Social. Portaria nº 3.046, de 20 de julho de 1982. **Reorientação da assistência à saúde no âmbito da Previdência Social.** Brasília: Gráfica do INAMPS, 1983. p.36-42.

BRASIL. **Constituição da República Federativa do Brasil**. Capítulo da Saúde, art.199, p.33. Brasília, 1988. Disponível em: http://www.senado.gov.br/sf/legislacao/const. Acesso em: 07 mar. 2006.

BRASIL. Lei 8080. Lei Orgânica da Saúde. Diário Oficial da União. Brasília, 1990.

BRASIL. Resolução INAMPS 273, de 17 de Julho de 1991. **Reedição da Norma Operacional Básica/SUS no. 01/91.** Brasília, 1991.

BRASIL. Ministério da Saúde. Portaria nº 234, de 07 de fevereiro de 1992. **Edição da Norma Operacional Básica do Sistema Único de Saúde para 1992 (NOB-SUS/92).** Brasília, 1992.

BRASIL. Ministério da Saúde. **Norma Operacional Básica do Sistema Único de Saúde - NOB - SUS 93.** Brasília, 1993a.

BRASIL. Ministério da Saúde. Portaria do Gabinete do Ministro da Saúde nº 1286, de 26 de outubro de 1993. **Diário Oficial Da União**. Brasília, 1993b.

BRASIL. Decreto nº 1.651, de 28 de setembro de 1995. Regulamenta o Sistema Nacional de Auditoria no âmbito do Sistema Único de Saúde. **Diário Oficial da União**. Brasília, 1995.

BRASIL. Ministério da Saúde. Portaria n. 2203, de 5 de novembro de 1996. Aprova a Norma Operacional Básica do Sistema Único de Saúde, NOB - SUS 01/96. **Diário Oficial da União**. Brasília, 1996.

BRASIL. Lei nº 9.656. Regulamenta a Saúde Suplementar no Brasil e dá outras providências. **Diário Oficial da União**. Brasília, 2 jun. 1998.

BRASIL. Lei nº 9.782, de 26 de janeiro de 1999. Define o Sistema Nacional de Vigilância Sanitária, cria a Agência Nacional de Vigilância Sanitária e dá outras providências. **Diário Oficial da União**. Brasília, 1999.

BRASIL. Lei nº 9.961, de 28 de janeiro de 2000. Cria a Agência Nacional de Saúde Suplementar - ANS e dá outras providências. **Diário Oficial da União**. Brasília, 2000. Seção Extra.

BRASIL. Instrução normativa nº 01, de 06 de abril de 2001. **Define diretrizes, princípios, conceitos e aprova normas técnicas para a atuação do Sistema de Controle Interno do Poder Executivo Federal.** Brasília, 2001.

BRASIL. Ministério da Saúde. Portaria do Gabinete do Ministro nº 373 de 27-02-2002. Aprova a Norma Operacional da Assistência à Saúde - NOAS - SUS 01/2002. **Diário Oficial Da União**. Brasília, 2002a.

BRASIL. Ministério da Saúde. Secretaria da Assistência à Saúde. Portaria nº 423, de 09 de Julho de 2002. **Diário Oficial Da União**. Brasília, 2002b.

BRASIL. Ministério da Saúde. Secretaria da Atenção à Saúde. Departamento de Regulação, Avaliação e Controle. Coordenação Geral de Regulação e Avaliação da Saúde. Caderno da SAS. **Orientações para Contratação de Serviços de Saúde.** Brasília, 2003.

CAMPOS, G. W. S. **Reforma da Reforma.** São Paulo: Hucitec, 1992.

CARVALHO, D. M. Grandes sistemas nacionais de informação em saúde: revisão e discussão da situação atual. **Informe Epidemiológico do SUS**. Ministério da Saúde, Fundação Nacional de Saúde, CENEPI. Brasília, ano IV, n.4, out/dez, 1997.

CASTRO, J. D. Regulação em saúde: análise de conceitos fundamentais. **Sociologias**, v.4, n.7, p.122-36, 2002.

CECÍLIO, L. C. O. Mecanismos de regulação adotados pelas operadoras de planos de saúde no Brasil. **Relatório** final da pesquisa. ANS/DIPRO/GGTAP. 2004.

CONTANDRIOPOULOS, A. P.; CHAMPAGNE, F.; DENIS, J. L.; PINEAULT, R. A avaliação na área de saúde: conceitos e métodos. In: HARTZ, Z. M. A. (Org.) **Avaliação em saúde:** dos modelos conceituais à prática na análise da implantação de programas. Rio de Janeiro: FIOCRUZ, 1997. p.29-47.

DONALDSON, C.; GERARD, K. **Economics of health care financing:** the visible hand. London: McMillan Press, 1993.

LEVCOVITZ, E. L.; LIMA, L. D.; MACHADO, C. V. Política de Saúde dos anos 90: relações intergovernamentais e o papel das NOBs. **Cienc. Saúde Coletiva**, v.6, n.2, p.269-91, 2001.

MAGALHÃES JR., H. M. **Regulação assistencial:** a busca de novas ferramentas no SUS para enfrentar o desafio de garantir a assistência com equidade. Belo Horizonte: Prefeitura Municipal, 2002. (Pensar BH - política social).

MAGALHÃES JR., H. M. O desafio de construir e regular redes públicas com integralidade em sistemas privado-dependentes: a experiência de Belo Horizonte. 2006. Tese (Doutorado) - Faculdade de Ciências Médicas, Universidade de Campinas, Campinas.

MALTA, D. C. Buscando novas modelagens em saúde, as contribuições do Projeto Vida e Acolhimento para a mudança do processo de trabalho na rede pública de Belo Horizonte, 1993-1996. 2001. Tese (Doutorado) - Faculdade de Ciências Médicas, Universidade Estadual de Campinas, Campinas.

MALTA, D. C.; CECÍLIO, L. C. O.; MERHY, E. E.; FRANCO, T. B.; JORGE, A. O.; COSTA, M. A. Perspectivas da regulação na saúde suplementar frente aos modelos assistenciais praticados. **Cienc. Saúde Coletiva**, v.9, p.433-44, 2004.

MATUS, C. Política, planificación y gobierno. Caracas: Fundación Altadir. 1987.

MCGUIRE, A.; HENDERSON, J. B.; MOONEY, G. **The economics of health:** an introdutory text. London: Routledge and Kegan Paul, 1992.

MERHY, E. E. A saúde pública como política. São Paulo: Hucitec, 1992.

MERHY, E. E.; FRANCO, T. B.; BUENO, W. S.; MAGALHÃES JR., H. M. **Trabalho em saúde:** olhando e experienciando o SUS no cotidiano. São Paulo: Hucitec, 2004.

OLIVEIRA, J. A.; TEIXEIRA, S. F. (In)previdência Social. Petrópolis: Vozes, 1986.

ORGANIZACION MUNDIAL DE LA SALUD - OMS. Organizacion Panamericana de la Salud - OPAS. **Evaluación de servicios de la salud materno-infantil.** Ginebra, 1989.

PAIM, J. S. Bases conceituais da reforma sanitária brasileira. In: FLEURY, S. (Org.) **Saúde e democracia:** a luta do CEBES. São Paulo: Lemos, 1997. p.11-24.

SANTOS, F. P. A regulação pública da saúde no Brasil: o caso da saúde suplementar. 2006. Tese (Doutorado) - Faculdade de Ciências Médicas, Universidade Estadual de Campinas, Campinas.

Translated by Flávia Maria Daou Lindoso da Fonseca. Translated from *Interface*[on line]. Jan./June 2006, vol.10, n.º.19, pp.25-41. ISSN 1414-3283.

^{*} Elaborated from Santos (2006). **Rua Augusto Severo, 84, 9° andar Glória - Rio de Janeiro, RJ Brasil - 20.021-