



Analysis of the financial impact of regulation for operators in the private healthcare sector

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Summary

This work's objective is to assess the impact on the healthcare expenditure of private health plans resulting from expansions made to the List of Health Procedures and Events, established by the Agência Nacional de Saúde Suplementar [National Regulatory Agency for Private Health Insurance and Plans] – ANS, between 2003 and 2013. We conducted a retrospective study based on the estimation of an econometric model with balanced panel data. The study points to the need for the deployment of quantitative methodologies of Regulatory Impact Analysis to support decision-making when incorporating new technologies, with a focus on sustainability in the private healthcare sector.

Key Words

private healthcare, regulation, regulatory impact analysis, expenditure on healthcare.

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Sinopse

Análise do impacto financeiro da regulação assistencial nas operadoras do setor de saúde suplementária

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Resumo

O objetivo deste estudo é avaliar o impacto com gastos de saúde de planos de saúde privados oriundos de expansões da Lista de Procedimentos de Saúde e Eventos, estabelecido pela Agência Nacional de Saúde Suplementar entre 2003 e 2013. Foi conduzido em estudo retrospectivo baseado na estimação de um modelo estatístico com dados em painel balanceado. O estudo aponta a necessidade de se estabelecer metodologias quantitativas de Análise de Impacto Normativo para apoiar a decisão quanto a incorporação de novas tecnologias, focando na sustentabilidade da indústria.

Palavras-chave

Saúde suplementária, regulação assistencial, gastos em saúde.

Sumário

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Sinopsis

Análisis del impacto financiero de la regulación asistencial en las operadores del sector de salud suplementaria

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Resumen

El objetivo de este estudio es evaluar el impacto del Rol de Procedimientos de Cobertura Obligatoria en los gastos asistenciales de las operadoras de planes de salud entre 2003 y 2013. Se llevó a cabo un estudio retrospectivo basado en la estimación de un modelo estadístico con datos en panel balanceado. El estudio señala la necesidad que se establezcan metodologías cuantitativas de Análisis de Impacto Normativo para apoyar la decisión en cuanto a la incorporación de nuevas tecnologías, centrándose en la sostenibilidad de la industria

Palabras-clave

Salud suplementaria, regulación asistencial, gastos em salud.

Sumario

1. Introducción. 1.1 El sector privado de la salud. 1.2 La lista de Procedimientos de Salud y Eventos. 1.3 Cualidade de la regulación y análisis del impacto regulador. 2. Métodos. 2.1 Modelos de Panel de Datos. 2.2 Especificación del modelo empírico. 3. Resultados. 3.1 Análisis Descriptiva. 3.2 El impacto de la ampliación de la lista de Procedimientos de Salud y Eventos: resultados del modelo empírico. 4. Discusión. 5. Conclusión. 6. Referencias Bibliográficas.



1. Introduction

The Agência Nacional de Saúde Suplementar [The National Regulatory Agency for Private Health Insurance and Plans] (ANS) was created by Law No. 9,961/2000 for the purpose of regulating and supervising the activities of healthcare providers who operate in that sector, including the relationship between the beneficiaries of private health plans and those providers, promoting the defence of the public interest and contributing to the development of the nation's health. (BRAZIL, 2000).

The activity of the ANS has its base in economic-financial regulation and healthcare, as well as structuring, supervision and quality induction. The economic regulation involves, basically, the expedition of operating permits, setting the solvency margin requirement and guaranteeing assets, definition of the percentage of annual adjustment applied to the contracts of individual or family plans, among other measures. (BAHIA and VIANA, 2002; PIETROBON *et al.*, 2008).

Healthcare regulation, in turn, is aimed at ensuring access to healthcare goods and services; something that, in itself, is a fundamental aspect of the right to health, laid down in the Constitution of 1988 (NOGUEIRA, 2002). Among the instruments used to achieve this goal is the List of Health Procedures and Events, which determines the minimum mandatory coverage available in health plans contracted after January 1999.

Since the establishment of the Agency, the List has undergone periodic reviews to ensure the inclusion of new procedures and medical technologies, this goal being justified by the evolution of medicine and healthcare practices (ANS, 2011a). The process of enlargement of mandatory coverage reflects, at least in part, the demands of providers and consumers of health services, but has faced resistance from the representatives of the operators, who argue that the cost increase of technological resources may compromise economic and financial sustainability in the long term (FIGUEIREDO, 2002; AKL, 2011).

CESCHIN (2011) asserts, however, that the adjustments applied to the monthly fees of the healthcare plans have been sufficient to offset the financial impact of the successive expansions made to the List and points out that its dimensioning should consider not only the direct cost of utilizing new technologies, but also the economic saving as a result of the procedures avoided. Hence, if a new diagnostic test is able to avoid future hospitalizations, it may bring lower costs for operators. Nevertheless, the author acknowledges that the ANS has no tools to assess prospectively the impact of any new regulation.

In fact, what is observed is that healthcare expenditure on the part of the operators has grown beyond their revenue in recent years, increasing the claims rate¹ from 79% in 2001 to 84% in 2013 (ANS, 2014). In addition to the expansion of mandatory coverages and inflation in the healthcare sector, usually higher than the general inflation rate, other factors

¹ Relationship between health care spending and revenues from healthcare plan premiums in cash.



have contributed significantly to the growth in spending, particularly the aging population and the changes in the epidemiological profile of the population, which impacts positively on the demand for medical care (CARNEIRO *et al.*, 2013).

In the centre of the debate about the quality and impact of its activities, the ANS included in its Regulatory Agenda for the biennium 2013/2014², the commitment to implement Regulatory Impact Assessment tools, based on the experience of other national and international entities. However, over this period, the ANS has yet to release any study assessing the impact of the expansion of the coverages provided in the List of Health Procedures and Events.

In this context, the present study aimed to assess the impact on the healthcare expenditure of private health plans resulting from expansions made to the List of Health Procedures and Events between 2003 and 2013.

1.1 The private health sector

In Brazil, the healthcare plan market started to develop in the 1950s and '60s, when several public companies took the initiative by intergrating their own resources and servants for the creation of funds intended to finance healthcare. In the private sector, foreign automobile manufacturers were the first to organize contributory plans, whose resources were directed towards the establishment and maintenance of medical services (primarily outpatient), and reimbursement of expenditure incurred in private hospitals and clinics. (BAHIA and VIANA, 2002).

Open plans for the purpose of profit began emerging in the 1960s, with emphasis on the role of specialist medical companies (Group medical and medical cooperatives), and expanded significantly in the 1980s, with the consolidation of large national insurers in the market, intensifying the marketing of individual employment plans and the accession of new groups of workers to collective plans (BAHIA and VIANA, 2002).

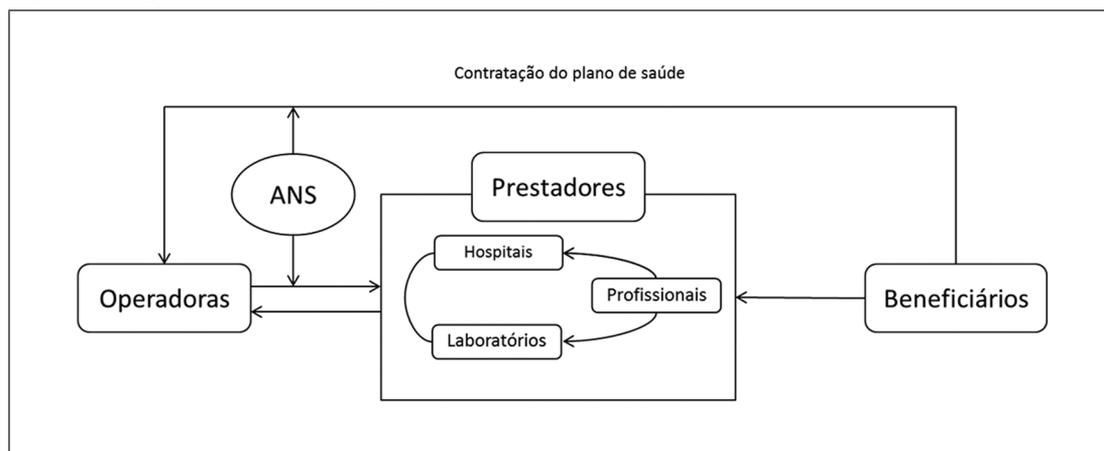
It was in this scenario of market expansion that the Federal Constitution of 1988 (BRAZIL, 1988), in addition to having established a national health system endowed with the principles of universality, comprehensiveness and equality, legitimized the role of private initiatives in the healthcare sector, under the control and supervision of the State. However, private healthcare only became the subject of State regulation from 1998, with the enactment of Law No. 9656/1998, the Lei dos Planos de Saúde [Healthcare Plan Law] (BRAZIL, 1998), which laid foundations for the creation, functioning and removal of operators, defining the standards of healthcare and segmentation, and setting out the essential and specific attributes of health plans.

² The Regulatory Agenda 2013/2014 is available at: <http://www.ans.gov.br/aans/transparencia-institucional/agenda-regulatoria>. Accessed on: 6 October, 2014.

Despite setting general guidelines for the functioning of the private healthcare sector, the healthcare plan law was transferred to the Executive Branch responsible for regulating and supervising the activities of the operators, allowing for the creation of the ANS through Law 9961/2000 (BRAZIL, 2000). The various functions of the ANS listed in Article 4 of the aforementioned legal framework, include: definition of the general characteristics of the contractual instruments of the plans; the creation of a list of mandatory minimum coverages; operation of the reimbursement to SUS, setting criteria for accreditation and disqualification of providers; authorize the expedition of adjustment of plan premiums; set rules for the granting, maintenance and cancellation of operators' registration, including with regard to proof of solvency and maintenance of related assets, etc.

Thus, the ANS arose out of the tremendous challenge of disciplining and controlling a market (Figure 1) that, at the time, already involved 30 million beneficiaries of healthcare plans, more than 2,000 operators and thousands of healthcare professionals (2).

Figure 1 – Agents involved in the private healthcare market



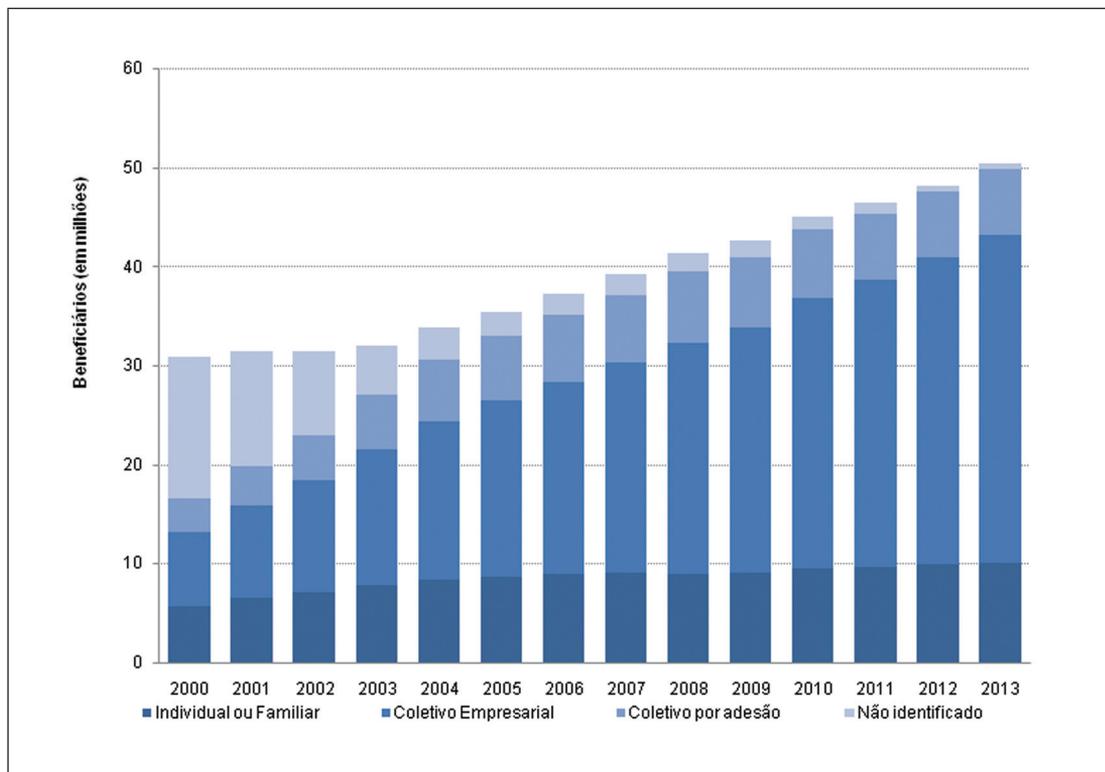
Source: own elaboration.

Since the establishment of the ANS, the number of users has grown substantially, surpassing 50 million – 26% of the Brazilian population (Figure 2). In this regard, we should note the growth of the corporate sector which, in December 2013, accounted for some 79% of the beneficiaries – 66% through companies with which it has an employment or statutory relationship (corporate membership) and 13% by legal entities of a professional character, by class or sector (group membership), while individual plans, whose membership is open to individuals, with or without a family group, amounted to 21% of health plan beneficiaries.

In relation to the coverage rate, there are interregional differences. In the Southeast, for example, the share of the population covered by the end of 2013 was 39%, highlighting the State of São Paulo, where this participation amounted to 45%. In the North and Northeast regions, the share of the population covered was substantially lower, at approximately 12% (ANS, 2014).

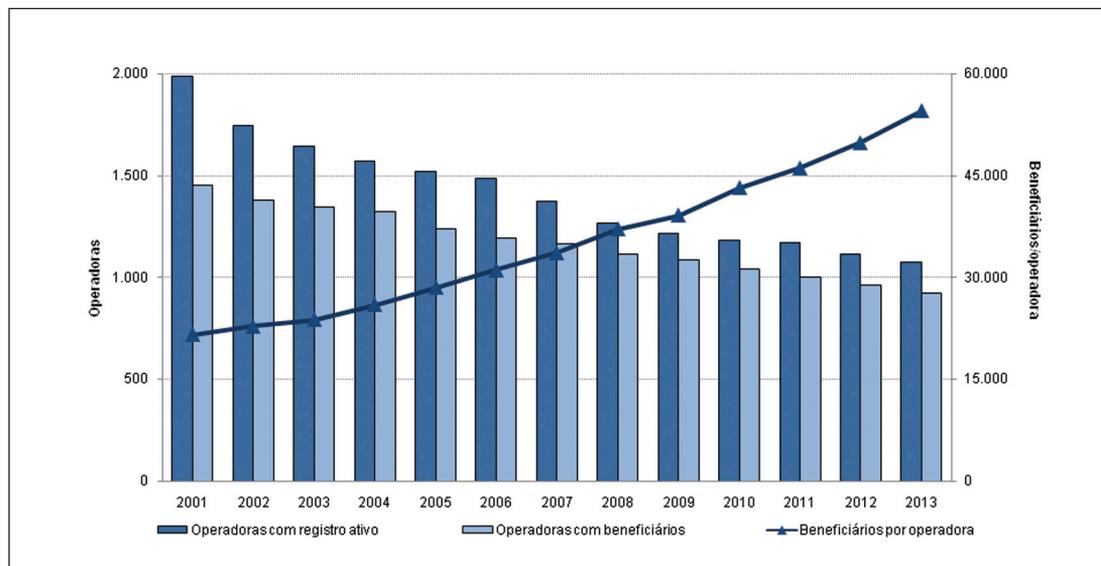
Despite the tendency for expansion in the population covered, the number of healthcare plan operators with active records has declined since the creation of the ANS, from 1,991 companies in 2001 to 1,076 in 2013, of which 922 have registered beneficiaries. What is observed, therefore, is the tendency towards market concentration: in 2001, each operator had, on average, 21,600 beneficiaries and, in 2013, this number reached 54,500 (Figure 3).

Figure 2 – Number of beneficiaries of healthcare plans according to type. Brazil, 2000 to 2013



Source: Own elaboration from data extracted from ANS TabNet. Accessed on 6 October, 2014.

Figure 3 – Companies in operation and with registered beneficiaries and average number of beneficiaries by provider. Brazil, 2001 a 2013



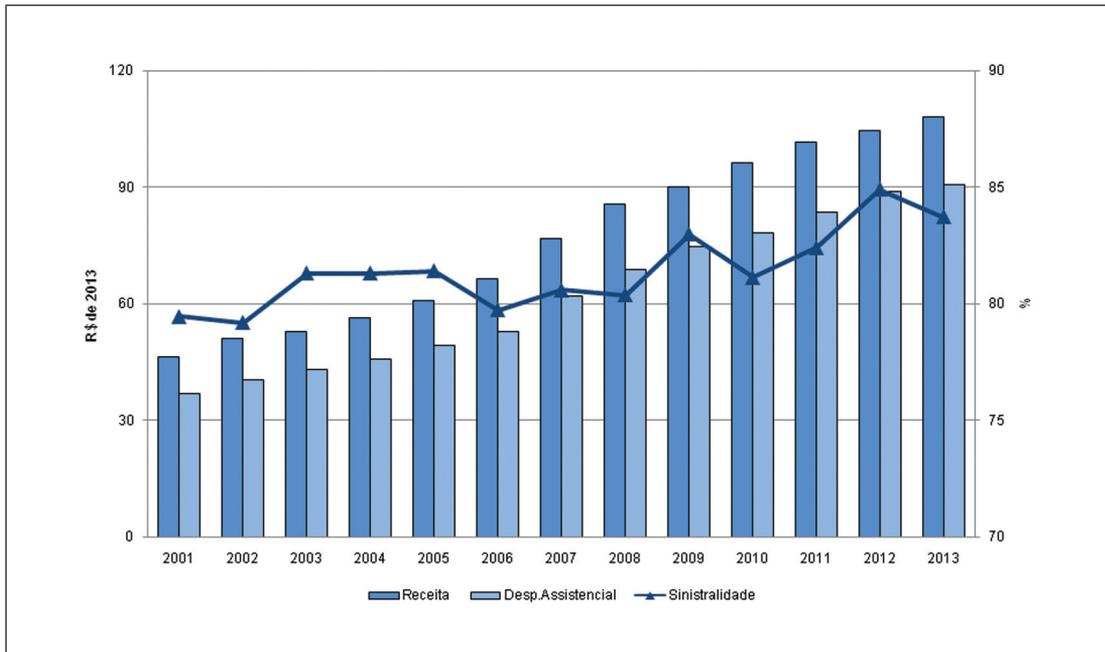
Source: ANS, 2014.

The expansion of the portfolio of beneficiaries has been reflected in the revenue of the operators, which has seen real growth of 133% between 2001 and 2013. The increase in revenue, however, was not sufficient to keep up with the growth of healthcare expenditure, of 146%, insofar as the rate of claims in the sector, which was 79% in 2001, reached 84% in 2013, as seen in Figure 4. Last year, the rate of hospitalization among beneficiaries of health plans was 13%, with average expenditure of R\$ 3,480.42 per event. Furthermore, each user had an average of 5.5 appointments, at an average cost of R\$ 40.30 to the health plan providers (ANS, 2014).

As for the service providers participating in the private health sector, in October 2014 there were 118,867 outpatient units (offices, clinics, laboratories) and hospitals (casualty or ER and clinical and/or surgical inpatient units) accredited/referenced by private health plans, according to the National Register of Health Facilities³.

³ Available at: http://cnes.datasus.gov.br/Mod_Ind_Unidade.asp. Accessed on: 6 October, 2014.

Figure 4 – Healthcare Revenue/Expenses (in R\$ for Dec/2013) and claims (%) for operators of private healthcare plans. Brazil, 2001 to 2013



Source: Own elaboration from data extracted from ANS TabNet, Accessed on 6 October, 2014.

1.2 The List of Health Procedures and Events

Although Law No. 9,656/1998 has, in general, provided the minimum mandatory coverage for healthcare plans, the impasses observed in individual cases gave rise to the development of specific regulations. Thus, in 1998, Private Health Council (CONSU) Resolution No. 10 established a basic list of mandatory coverage for the procedures of health plans contracted from January 2, 1999. After the creation of the ANS, this first list, whose implementation by participants in the market was still very limited, has since been updated by Collegiate Board Resolutions (RDC's) No. 41/2000 and No. 67/2001 (CICAD, 2014).

In 2004, the list of medical procedures for which coverage is mandatory was reissued by Normative Resolution (RN) No. 82/2004, when it gained the title of List of Health Procedures and Events. Later, this was updated by RN No. 167/2008, 211/2010 (amended by RN No. 262/2011) and No. 338/2013.

The List specifies all the various types of consultations, diagnostic tests and clinical and surgical procedures that must necessarily be offered by health plans, according to their healthcare segmentation, outpatient, hospital: (with or without obstetrics) or dental care. Thus, it seeks to ensure coverage for the procedures deemed necessary to the diagnosis and treatment of all diseases that make up the International Classification of Diseases – ICD-10. As this refers to the minimum level of care, there is no legal restriction on the plans providing greater coverage than described (ANS, 2011a).



Periodic reviews of the List have targeted, especially, the inclusion of procedures proven to be safe and effective (with or without utilization guidelines) and the exclusion of those that are obsolete or have insufficient validation, in addition to the amendment and/or expansion of existing guidelines for use, and the incorporation of measures for the prevention and the promotion of health, anchored in the principles of evidence-based medicine with a view to aligning health policies (ANS, 2011a; CIDAD, 2014).

Proposals for updating the List are developed by a technical group composed of representatives of consumer organizations and healthcare providers, healthcare professionals and servants of the ANS, which are then subjected to evaluation by society through public consultation with open participation for all interested parties. The idea, therefore, is that the List does not constitute an imposition by the ANS but, rather, something that reflects the aspirations of the most diverse social groups (CESCHIN, 2011).

The main innovations arising from updates to the List are described below:

- RN No. 82/2004, in force from 29/09/2004 (ANS, 2004): amalgamated the classification of procedures used in the previous list with the Brazilian Hierarchical Classification of Medical Procedures and adopted a more streamlined format, making the instrument more intelligible to the operators and providers of healthcare services. This work did not result in a reduction or expansion of healthcare coverage, but merely removed duplicate titles and performed various logical adjustments.
- RN No. 167/2008, in force from 02/04/2008 (ANS, 2008): added 109 new procedures to the previous list, among those which stand out: appointments/sessions for physiotherapy, nutrition, occupational therapy, psychotherapy and speech therapy; birth control procedures, such as vasectomy, tubal ligation and intrauterine devices (IUD); surgical procedures by video, autologous stem cell transplantation, gastroplasty and surgical treatment for epilepsy, hydrocephaly and cerebral cysts; diagnostic tests for the molecular analysis of DNA, digital mammography, mammotomy, among others. The new List also assured the coverage of costs of a companion for hospitalizations of children under 18 years, the elderly and people with special needs.
- RN No. 211/2010, in force from 07/06/2010 (ANS, 2011b): added 72 new procedures to the compulsory coverage list, among these, allogeneic stem cell transplantation; the surgical treatment of heart failure with pacemaker implantation; 26 new thoracic video surgeries and 17 laboratory tests, including antibody dosages and new genetic and imaging tests, especially the Pet-Scan for cancer. RN No. 211/2010 was amended by RN No. 262/2011, which came into force on 01/01/2012. This new normative has determined the inclusion on the list of a further 69 procedures, among these, 41 video surgeries, and deleted five others.



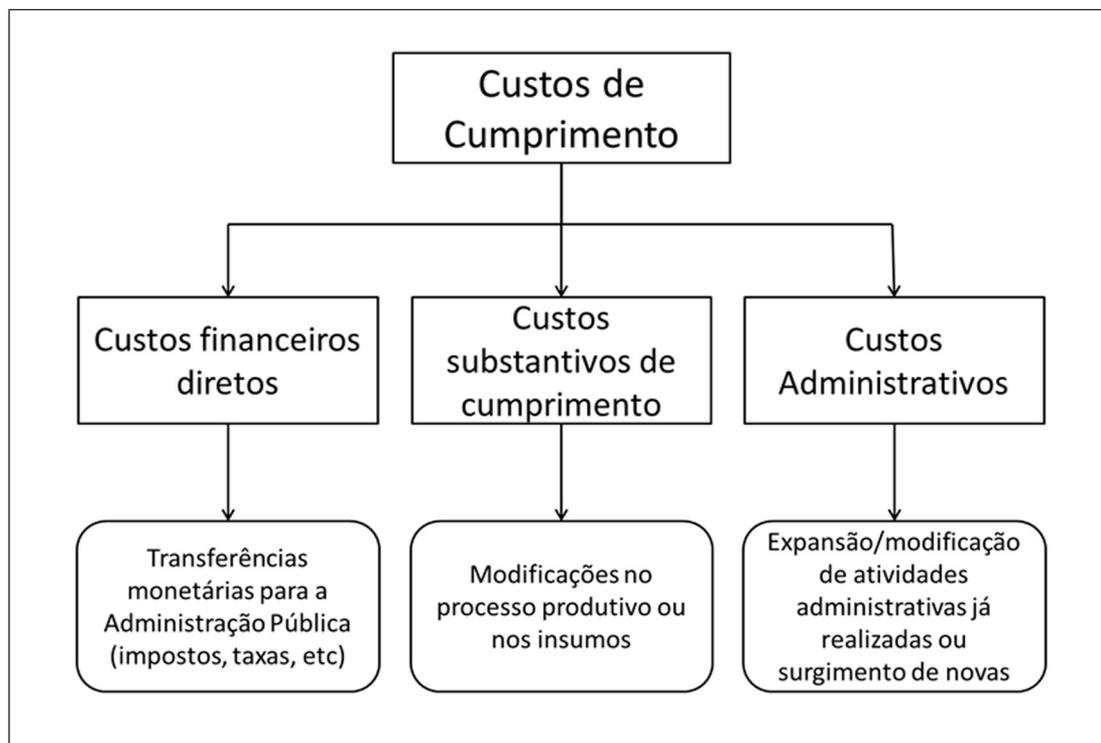
- RN No. 338/2013, in force from 02/01/2014 (ANS, 2013): incorporated 87 new procedures, including 37 oral medications for home treatment of cancer and 28 minimally invasive surgical procedures (video laparoscopy and radio frequency). It established the mandatory provision of intestinal or urinary collection bags for patients with ostomies and expanded the guidelines for the use of 44 procedures that were already in the previous listing, such as as the Pet-Scan for cancer, which received five new recommendations – detection of solitary pulmonary nodule, metastatic breast cancer, head and neck cancer, melanoma and esophageal cancer.

1.3 Quality of regulation and regulatory impact analysis

Despite the recognition that State regulation plays an important role in the mitigation of market failures and the implementation of public policies, we cannot disregard the high costs imposed by regulatory activity on the entities being regulated and to society as a whole (OECD, 2008b). For those, the cost of regulation (compliance costs) can be classified into (INTERNATIONAL SCM NETWORK, 2005):

- Financial costs resulting from the direct transfer of sums to the Government or the regulator through the payment of fees and charges. Among these costs, the fees for operator registration or registration of new products with the regulator are the most obvious.
- Substantial compliance costs: arising from the adjustment of the productive activity to the standards issued by the regulator. Examples include the costs derived for the adaptation of buildings and facilities to meet the standards of public health or, in the case of private health plan operators, the expansion, by the ANS, of the List of minimum mandatory coverage.
- Administrative costs derived from the creation/expansion of administrative activities as required by the regulator or to suit its requirements. These constitute costs, among others, derived from routines created for the exchange of information with the regulator.

Figure 5 – Compliance costs for the regulated agents



Source: adapted from International SCM Network, 2005

It is estimated that in the United States, the cost of complying with federal regulations represents 7.2% to 9.5% of GDP and in the United Kingdom, such participation is 10% to 12% of GDP (HAHN, 2000; BRTF, 2005). Despite the absence of specific studies, PROENÇA and RODRIGO (2012) point out that, in developing countries, where regulatory frameworks tend to be more complex, compliance costs can represent even larger loads.

Not by chance, several international bodies, such as The Organisation for Economic Co-operation and Development (OECD, 2008b) have advocated the adoption of regulatory practices as a way to strengthen governance, reduce unnecessary regulatory burdens and stimulate competition and investment, which are essential to economic development.

Although there is no precise definition, PROENÇA and RODRIGO (2012) define “good regulation” as that which is capable of achieving its goals at the lowest social cost in the most simple, transparent and responsible way possible. As a result of the search for quality regulation, several countries have adopted tools to support decision-making, among those that stand out is the Regulatory Impact Analysis (RIA), which aims to examine systematically the benefits, costs and risks of a new regulation (ex-ante) or one that already exists (ex-post).



The United States pioneered the systematic adoption of RIA in the 1970s and, by 2005, all OECD countries were using at least one regulatory impact assessment technique. The recommendation is that RIA be integrated from the early stages in the formulation of new regulatory proposals, in order to clearly identify the objectives of the proposal, evaluate whether the intervention is necessary, effective and efficient in achieving those objectives, and identify alternative options and trade-offs involved (OECD, 2012).

Various methodologies are used, alone or in combination, with the RIA, depending on the political, cultural and social characteristics of each country and the availability of resources. The qualitative approaches include checklists and matrices, widely used in European Union countries, such as the Netherlands, Ireland, Spain and Switzerland. However, quantitative methodologies are the most common and valued because they permit more clear and objective decision-making. Among them, it is possible to highlight (OECD, 2012):

- **Cost-benefit analysis (CBA):** consists of a comparison of the costs and benefits of regulation, both valued monetarily. Based on the CBA, regulation is appropriate when its social benefits exceed the costs imposed to the economic agents involved. Similarly, when comparing two regulatory options (incremental cost-benefit analysis), the most suitable is the one that generates the highest net benefit.

Despite the limitations related to the quantification and monetization of costs and benefits, the CBA is the most widespread quantitative method used in developed countries. In the US, for example, the conducting of a CBA is mandatory whenever the standard has an estimated impact higher than \$ 100 million per year; or when increased costs are imposed for a specific sector or region; or when there is a significant adverse effect on competition, employment, investment, productivity or innovation. (ALVES and PECCI, 2011).

In this country, all CBA's are subject to the *Office of Information and Regulatory Affairs* (OIRA), which as a supervisory organ of the implementation of public policies, can veto the publication of regulations whose costs do not present appropriate counterparts in terms of benefits.

- **Cost-effectiveness analysis (CEA):** different to CBA, does not presuppose that the benefits are expressed in the same units as the costs. Thus, while the costs are monetized, the benefits can be expressed in natural units. It is used generally when the regulatory benefits are hard to assess or when there is a need to compare regulatory options that generate similar benefits in order to identify the least costly (incremental cost-effectiveness analysis). The OECD (2008b) defines the CEA as a limited method, as it does not consider whether the benefits of an intervention justify its costs.



- Partial analysis (PA): assess regulatory impacts from the perspective of a particular segment or interest group. The European Commission has adopted the Standard Cost Model, that proposes to identify and measure administrative costs imposed on regulated agents. The focus on that portion of the cost of compliance stems from the commitment of the European countries to eliminate regulations that generate excessive and unnecessary administrative burdens, encouraging the development of more efficient economies (INTERNATIONAL SCM NETWORK, 2005).

In Brazil, as well as in most developing countries, the actions aimed at improving the regulatory governance are incipient (QUEIROZ-CUNHA and RODRIGO, 2012). A report by the OECD (2008b) states that the agencies were fundamental in reducing regulatory uncertainty and for the economic and social development over the past decade, citing the expansion of access to basic services such as electricity, telephone and health, but notes that some challenges remain, such as the improvement of the institutional design and the systematic adoption of transparency, accountability and social control.

QUEIROZ-CUNHA and RODRIGO (2012) cite fragmentation and the lack of political leadership as two of the main obstacles to institutional modernization and strengthening the capacity of agencies to regulate quality. In this sense, the creation of the Institutional Capacity Building Programme for Regulatory Management (PRO-REG), through Decree No. 6,062/2007, represented an important development. Coordinated by the Civil Office, the program has the purpose of contributing towards the improvement of the regulatory system, coordinating the institutions that exert regulatory activities under the Federal Government and mechanisms of accountability, participation and monitoring by the civil society.

Since its creation, PRO-REG has supported the implementation of RIA, together with the regulatory agencies, as a tool to aid decision-making. The pioneer was Anvisa, who developed, within the framework of the Good Regulatory Practices Program (established by Ordinance No. 422/2008), a checklist for identifying the impacts in terms of costs and benefits, or the regulatory proposal or existing standard for the various players involved. (RAMALHO, 2009).

Based on this first experience, RIA has spread to other agencies and, currently, almost all of them already make some use of this instrument (PROENÇA and RODRIGO, 2012). The OECD (2008a) points out, however, that the methodologies used are usually incomplete and rarely involve some kind of systematic quantitative analysis, since RIA is still perceived as an expensive tool that does not produce the results expected in the short term.



The ANS, an agency with special interest in this work, has committed itself publicly to RIA themes and has included them on its Regulatory Agenda for the years 2013 and 2014, in the axis of Regulatory Governance. At the end of this period, some advances have been achieved, such as the Executive Summary of Regulatory Impact, an instrument aimed at identifying the potential effects of new regulatory options. However, in line with other agencies, the ANS has yet to release any study to assess quantitatively the impact of the regulations produced.

2. Methods

This is a retrospective study based on the estimation of an econometric model with balanced panel data for the healthcare spending of 583 operators who were active and had beneficiaries registered with the ANS during the period of 2003 to 2013, at a national level.

The hypothesis of this study is that the evolution of the expenditure of the health plan operators was influenced by the expansion of the List of Health Procedures and Events, being crucial to evaluate the magnitude of this effect.

2.1 Panel Data Models

By combining data arranged in time series and cross-sections, models with panel data (or longitudinal) allow simultaneous exploration of both sectional (or spatial) and temporal variations.

Among the advantages of estimation with longitudinal data, there is the ability to control the heterogeneity, to the extent that it may be considered in the analysis of distinguishing characteristics of observation units, which may or may not vary over time and that when discarded, tend to produce biased results. Moreover, as mentioned by Wooldridge (2002), the panel organization provides higher data variability, the less collinearity between variables, the greater number of degrees of freedom and greater efficiency in estimation.

The panel data models are presented in general as follows:

$$Y_{it} = \alpha + X_{it} \beta + \varepsilon_{it} \quad (1)$$

In which α represents the intercept, X the set of explanatory variables and ε the error term. The sub-indices i and t denote the observational unit and the length of time, respectively. When, for each unit i , there is the same number of temporal data, the panel is balanced, as in this study. Otherwise, if the number of temporal data is not the same for all individuals, the Panel is unbalanced.



Two basic models are derived from the equation (1): a fixed effect (FE) and a random effect (RE). The FE model assumes that unobservable individual effects are correlated with the set of explanatory variables and that adequate estimation of parameters requires control of this correlation. To this end, it considers that all the heterogeneity (observable or not) is captured by the intercept, which differs from unit to unit. Formally:

$$Y_{it} = \alpha_i + X_{it}\beta + \varepsilon_{it} \quad (2)$$

In which α_i represents the intercept for each unit. Under the assumption of strict exogeneity, parameters can be estimated consistently by the method of Grouped Ordinary Least Squares.

In practice, the models with FE have the disadvantage that it is impossible to include them in the model variables that remain constant over time, causing an important loss of degrees of freedom.

The models with RE assume that there is no correlation between the individual effects and the explanatory variables and therefore use an estimation process where the heterogeneity between the transverse units is captured in the error term, according to the following equation:

$$Y_{it} = \alpha + X_{it}\beta + \mu_{it} \quad (3)$$

In which μ_{it} is the composite error term, such that $\mu_{it} = \eta_i + \varepsilon_{it}$, with η_i being the individual unobservable effect and α represents the common average for all intercepts of observation units. In models with RE, the parameters can be obtained consistently and unbiased by the method of Generalized Least Squares (WOOLDRIDGE, 2002).

Therefore, the preference between FE and RE depends on the objectives of the research and the availability of information. By not allowing estimates related to invariant characteristics in time, FE models are most suitable when the central purpose of the analysis falls on the variations observed in each transverse unit over time (variations within or intra-group). In a different way, the estimates with RE enable the modelling of individual observable characteristics and are therefore preferable when the objective of the study involves the measurement of the effects related to these differentiating features (variations between or inter-group).

However, the crucial factor in deciding the model to be used refers to the assumption about the possible correlation between the error term and the set of explanatory variables: if they are not correlated, the RE will be most suitable; if they are correlated, FE will be more appropriate. A more formal test can be performed to support the decision, such as the Hausman test, which has, as a null hypothesis, the assumption of no correlation between the error and the covariates (HAUSMAN, 1978).

In this work, the hypothesis that the structural and regional characteristics of the operators affect healthcare spending implies the use of the model with RE. Nevertheless, the model with FE was also estimated and subsequently subjected to a Hausman test in order to identify the most appropriate approach to the empirical model constructed.



2.2 Specification of the empirical model

To assess the impact on the healthcare expenditure of private health plans resulting from expansions made to the List of Health Procedures and Events, an econometric model with panel data was derived for the years 2003 and 2013, where the dependent variable was the natural logarithm of annual healthcare expenditure per capita (at prices from December 2013) for each of the 583 operators included in the analysis.

For construction of this variable, the data of annual healthcare expenditure by operator was utilized, available at ANS TabNet⁴, and the information of the number of beneficiaries by operator at the end of each year, solicited directly by the ANS through the Electronic System of the Citizens Information Service (e-SIC), which is supported by the Access to Information Act (Law No. 12,527/2011). The monetary values were corrected for December 2013 values by the Consumer Price Index (IPCA-IBGE).

As for the regressions, in addition to the enlargement of the list of mandatory coverage, variables related to structural and regional characteristics of the operators and to the economic growth observed in the period were also selected, included in the model as control variables.

The explanatory variables entered in the analysis and their expected effects on annual per capita healthcare expenditure are specified below and resumed in Frame 1.

- 1) **Duration of the RN's that have updated the List of Health Procedures and Events:** was included in the model as a proxy for the expansion of mandatory minimum coverage for health plans, in the form of three binary variables – one for RN No. 82/2004 (2005 to 2007), one for RN No. 167/2008 (2008 to 2010) and one for RN 211/2010, altered by RN No. 262/2011 (2011 to 2012). The references were the years of 2003 and 2004, the period in which the CONSU No. 10 was in effect, altered by RDC's No. 41/2001 and No. 67/2001. A positive impact of the dummies *RN82*, *RN167* and *RN211* was expected.

It should be noted that, for the years in which there was a transition from one RN to another, there was only one that had its effects for the longest period of time. In 2008, for example, RN No. 82/2004 was valid until April 2, when RN No. 167/2008 entered into force. So this year was considered as a period of validity of the latter Normative, which generated effects for almost nine months.

⁴ Available at: http://www.ans.gov.br/anstabnet/cgi-bin/dh?dados/tabnet_rc.def. Accessed on: 23/09/2014. Accessed on: 23 September, 2014.



2) **Modality (Type):** characteristic concerning the form and the purpose of the operator and, therefore, time invariant. According to the classification established by RDC No. 39/2000 (ANS, 2000), there are six modalities of healthcare plan operators:

- Specialized health Insurers: businesses under the modality of for-profit insurance companies. Their products must offer, mandatorily, the option of free choice of service providers, with subsequent reimbursement of the expenditure incurred, in accordance with the limits in contract.
- Medical cooperatives: companies incorporated under Law 5.764/1971 (General Law of Cooperatives). Although not-for-profit, the positive economic result is distributed among the cooperating medics that are, at the same time, partners of the operator and service provider.
- Philanthropic: non-profit operators, holders of the charity certificate of social care issued by the Ministry and a declaration of public utility by the Ministry of Justice or by the organs of the State and Local Governments.
- Self-management: non-profit entities that maintain health plans exclusively for current employees of one or more companies as well as for retirees, pensioners or former employees, and their dependents.
- Group Medical: operators that are in the form of a profit-oriented society, except those classified in the other modalities.
- Administrator: company that administers plans held by another operator and, therefore, has no beneficiaries, does not assume the risk arising from the operation of those plans, and does not have its own network for accredited or referenced medical services.

The operator type was entered in the model by means of four dummy variables (*mod_medicina*, *mod_cooperativa*, *autogestao* and *mod_filantropia*). The reference group consisted of specialized health insurers, which, according to the ANS data (2014), are the operators with the highest average cost per episode of hospitalization and medical consultation. The Administrators were not included in the analysis because they lack beneficiaries and, therefore, do not incur healthcare expenses. Thus, it was expected that the type dummies have a negative impact on the expenditure per capita variable.

The information on the type of operators was obtained directly from ANS Tabnet⁵.

⁵ Available at: http://www.ans.gov.br/anstabnet/cgi-bin/dh?dados/tabnet_03a.def. Accessed on: 23 September, 2014.



- 3) **Region in which the operator is headquartered:** proxy of the company's area of operation was included in the analysis by means of four binary variables in order to identify regional differences in expenditure of healthcare operators. The reference region is the Southeast which, according to the data from Pesquisa Nacional por Amostra de Domicílios [National Household Sample Survey] (PNAD) of 2008 (IBGE, 2010), had the highest rates of hospitalizations and medical consultations. Therefore, it was expected that the dummies for the North (*regiao_N*), Northeast (*regiao_NE*), South (*regiao_S*) and Central-West (*regiao_CO*) regions had a negative impact on healthcare expenditure per capita.

The information about the location region of the Head Office of health plan operators is available in ANS TabNet⁶.

- 4) **Size of operator:** modelled in the form of two binary variables, for the medium and large sizes, and with small business being the reference group. ALVES (2009) has shown that the smaller operators are less efficient, including with regard to their healthcare costs, by their inability to take advantage of economies of scale. Hence, it was expected that the *porte_medio* and *porte_grande* dummies had a negative effect on the dependent variable. Unlike the type and the location of headquarters, the size of the operator can change over time.

For categorization of operators according to range of beneficiaries, the criterion used by the NSA (2014) was adopted, namely:

- Small business: less than 20,000 beneficiaries
- Medium business between 20,000 and 99,999 beneficiaries
- Large business: 100,000 or more beneficiaries

- 5) **GDP per capita:** proxy of economic growth was inserted in the form of a logarithmic variable (*ln_pibpc*). The GDP per capita values were obtained from the IBGE⁷ website and corrected for December 2013 values by IPCA-IBGE. Several studies have shown that public and private expenditure on healthcare tends to follow the growth of the economy (CARNEIRO *et al.*, 2013; GETZEN, 2000; FIOCRUZ, 2012). Therefore, it was expected that the GDP per capita was positively associated with healthcare expenditure per capita.

⁶ Available at: http://www.ans.gov.br/anstabnet/cgi-bin/dh?dados/tabnet_03a.def. Accessed on: 23 September, 2014.

⁷ Available at: <http://seriesestatisticas.ibge.gov.br/series.aspx?vcodigo=SCN55&t=produto-interno-bruto-capita>. Accessed on: 6 October, 2014.



Frame 1 – Description of explanatory variables and their expected effects on healthcare expenditure per capita.

Variable	Description	Expected Effect
<i>RN82</i>	Validity of RN No. 82/2004 = 1; otherwise = 0	+
<i>RN167</i>	Validity of RN nº 167/2008 = 1; otherwise = 0	+
<i>RN211</i>	Validity of RN No. 211/2010= 1; otherwise = 0	+
<i>mod_medicina</i>	Group Medicine = 1; otherwise = 0	–
<i>mod_cooperativa</i>	Medical Cooperative = 1; otherwise = 0	–
<i>mod_autogestao</i>	Self-management = 1; otherwise = 0	–
<i>mod_filantropia</i>	Philanthropic = 1; otherwise = 0	–
<i>porte_medio</i>	Medium = 1; otherwise = 0	–
<i>porte_grande</i>	Large = 1; otherwise = 0	–
<i>regiao_N</i>	North Region = 1; otherwise = 0	–
<i>regiao_NE</i>	Northeast Region = 1; otherwise = 0	–
<i>regiao_CO</i>	Central-west Region = 1; otherwise = 0	–
<i>regiao_S</i>	South Region = 1; otherwise = 0	–
<i>ln_pibpc</i>	Natural logarithm of GDP per capita	+

In the model with FE, we used the t Test for the analysis of individual significance of the parameters and the F-test for the analysis of joint significance. In the estimation with RE, the individual and joint significance were assessed by means of the z Test and Wald test, respectively.

The levels of significance adopted were 1%, 5% and 10%. All descriptive and statistical analyses were performed using the statistical package Intercooled Stata 11.1.

3. Results

3.1 Descriptive analysis

Most of the 583 operators included in analysis were classified in the cooperative medical modality (47.7%) and group medicine (32.3%), while specialized health insurers were less representative, with only 1.9% of operators. Those headquartered in the Southeast, South, and Central-West, together amounted to 88.7% of companies (Table 1).

Table 1 – Distribution of operators by type and region headquartered. Operators analysed, 2003 to 2013

Type		n	%
	Self-management	46	7,89
	Cooperative	278	47,68
	Philanthropic	60	10,29
	Group Medical	188	32,25
	Insurer	11	1,89
Head Office Region			
	South	107	18,35
	Southeast	273	46,83
	Central-West	137	23,50
	Northeast	46	7,89
	North	20	3,43
Total		583	100,00

Between 2003 and 2013, the number of beneficiaries linked to the operators under scrutiny grew by 107.1%, from 20.6 to 42.6 million (Figure 6). The greatest expansion was with group medical (126.9%), followed by medical cooperatives (104.7%) and specialized health insurers (96.0%), while the self-management saw a shrinkage of 7.0% in its portfolio of beneficiaries. In the same period, total revenue of the operators had real growth of 131.2%, from R\$ 39.1 to R\$ 90.4 billion, while healthcare spending increased by 125.8%, from R\$ 33.0 to R\$ 74.6 billion, so that the overall claims rate of the operators under scrutiny was reduced from 84.5% in 2003 to 82.5% in 2013 (Figure 7).

Figure 6 – Distribution of beneficiaries according to operator type. Operators reviewed, 2003 to 2013

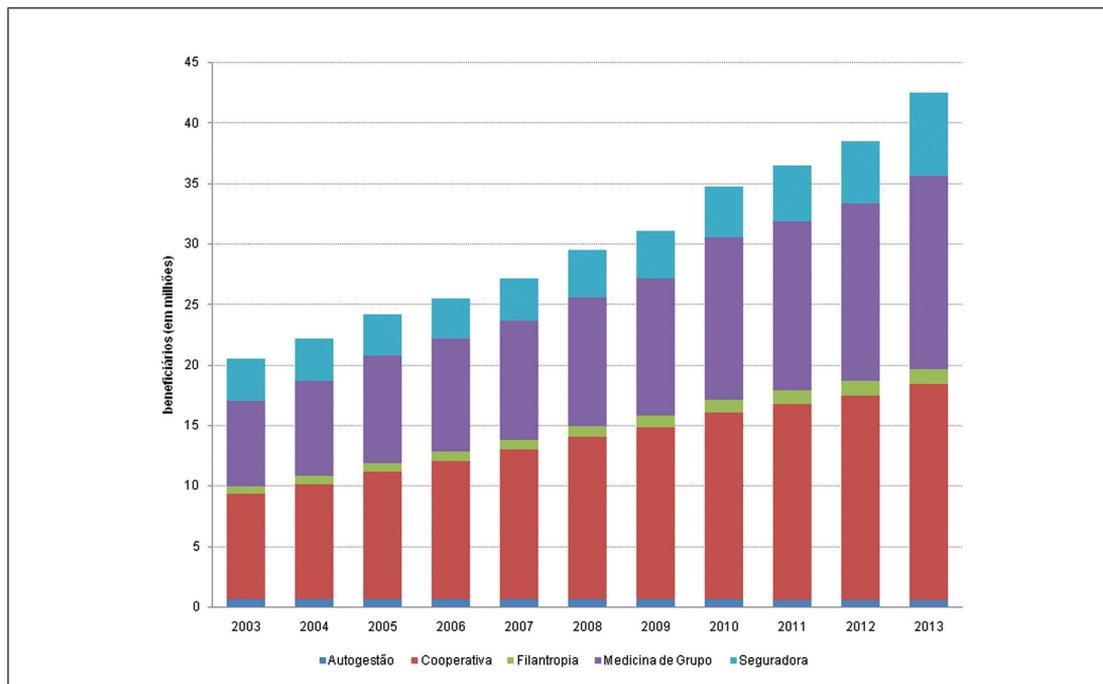
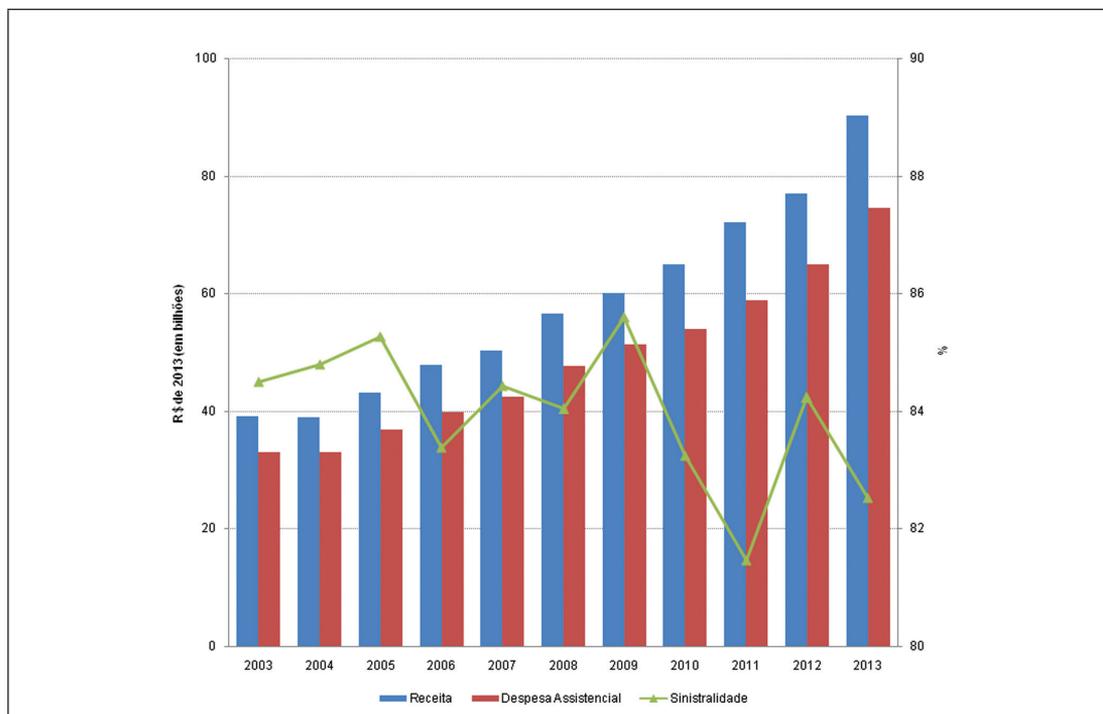


Figure 7 – Revenue and annual expenditure (R\$ from Dec/2013) and claims rate (%). Operators analysed, 2003 to 2013





In per capita terms, however, revenue growth was lower than expenditure: while the average annual ticket (relation between income and the number of beneficiaries) had real growth of 2.6%, the annual healthcare expenditure per capita increased to 7.3% (Table 2). The self-management operators had the higher average ticket growth (122.6%) and spending per capita (122.3%), followed by group medicine and insurers specialized in health. Conversely, there was a downward trend in spending per capita among medical cooperatives and philanthropic. The superiority of spending and revenue from specialist health insurers in relation to other disciplines during the whole period should be noted.

The same difference in revenue and expenditure developments can be observed in relation to the size of the operator: for the small business, the average ticket grew 10.5% and per capita spending 18.3%, while for the medium and large companies, the growth of spending and revenue was less expressive, as noted in Table 2.

Table 2 – Annual health care spending per capita, average annual ticket (R\$ from Dec/2013) and their variations (%) by type and size. Operators analysed, 2003 and 2013

Type	2003 (R\$)		2013 (R\$)		Variation (%)	
	Spent	Ticket	Spent	Ticket	Spent	Ticket
Self-management	1.436,18	1.621,22	3.193,16	3.609,19	122,34	122,62
Cooperative	2.481,06	2.963,95	2.153,13	2.507,12	-13,22	-15,41
Philanthropy	1.170,81	1.553,21	1.112,84	1.418,99	-4,95	-8,64
Group medical	932,87	1.306,70	1.361,87	1.687,58	45,99	29,15
Insurance company	3.122,67	3.575,97	3.890,63	4.086,47	24,59	14,28
Size						
Small	1.900,29	2.362,67	2.249,45	2.611,74	18,37	10,54
Medium	1.441,38	1.732,68	1.462,90	1.780,88	1,49	2,78
Large	1.584,37	1.879,66	1.720,02	2.042,92	8,56	8,69
Total	1.776,63	2.189,95	1.905,75	2.247,61	7,27	2,63



3.2 The impact of enlargement of the List of Health Procedures and Events: results of the empirical model

As already described, the effect of the explanatory variables on healthcare per capita expenditure for healthcare plan operators was evaluated for the period 2003 to 2013, through the estimation of panel data models with fixed effects (FE) and random effects (RE), whose results are presented in Table 3. For both models, the estimated parameters were statistically significant at the 1% level.

Table 3 – Results of the models with panel data with RE and FE.

	Random Effects			Fixed Effects		
	Coefficient	p-value		Coefficient	p-value	
<i>RN82</i>	0,09188	0,000	*	0,09251	0,000	*
<i>RN167</i>	0,11422	0,005	*	0,11474	0,004	*
<i>RN211</i>	0,19742	0,000	*	0,19819	0,000	*
<i>mod_medicine</i>	-1,33134	0,000	*		omitted	
<i>mod_cooperativa</i>	-0,70092	0,001	*		omitted	
<i>mod_autogestao</i>	-0,69082	0,003	*		omitted	
<i>mod_filantropia</i>	-1,22953	0,000	*		omitted	
<i>porte_medio</i>	-0,19064	0,000	*	-0,23652	0,000	*
<i>porte_grande</i>	-0,30692	0,000	*	-0,40904	0,000	*
<i>regiao_N</i>	0,06378	0,688	+		omitted	
<i>regiao_NE</i>	0,11949	0,277	+		omitted	
<i>regiao_CO</i>	0,41007	0,000	*		omitted	
<i>regiao_S</i>	-0,11217	0,153	+		omitted	
<i>ln_pibpc</i>	0,24351	0,074	***	0,26911	0,048	**
<i>_cons</i>	5,58070	0,000	*	4,29899	0,001	*
R ²	Between			0,1843		0,0214
	Within			0,0700		0,0708
	Overall			0,1618		0,0011
	Wald chi2(14)		568,60	F(6,5824)		73,93
	Prob> chi2		0,000	Prob> F		0,000
Hausman	Chi2(6)		41,80	Prob> chi2		0,000

Notes: + Not significant;
*** Significant to 10%;
** Significant to 5%;
* Significant to 1%.



The Hausman test rejected the null hypothesis that the explanatory variables and the error are not correlated and thus indicated that the regression with FE can be a more efficient estimator for the parameters. However, there were no significant differences between the estimates of the models with both FE and RE with regard to parameters such as the magnitude of statistical significance.

Moreover, as discussed earlier, the interest in measuring the impact of institutional and regional characteristics of the operators on the healthcare spending per capita necessarily implies the model estimation with RE in order to evaluate the influence of variables that remain constant over time such as the modality and region where the operator is headquartered. In this model, the explanatory variables tested accounted for 18.43% of the temporal variation (between or inter-group) and 7.00% of the sectional variation (within or intra-group) of the healthcare expenditure per capita. In the period analysed, there was a positive association statistically significant to 1% between the List of Health Procedures and Events and the healthcare expenditure per capita, as expected.

The validity of RN No. 87/2004 implied expenditure 9.19% higher, on average, in relation to the reference period from 2003 to 2004, when the minimum mandatory coverage was determined by CONSU Resolution No. 10/1998 and its updates. RN Nos. 167/2008 and 211/2010, had an impact of 11.42% and 19.74% respectively in relation to the initial regulatory situation. From these results, the effect of each RN in relation to the List immediately preceding can be inferred: 9.19% for No. 87/2004, 2.05% for No. 167/2008 and 7.47% for the No. 211/2010.

The modality dummies, in turn, were negatively associated with the dependent variable ($p < 0,01$). Among them, group medical and philanthropic stand out which had, on average, healthcare spending per capita of 133.13% and 122.95% lower than the reference group, formed by the insurers that specialize in health. Similarly, the binary variables assigned to medium and large operators also had a negative impact on spending in relation to small businesses.

In relation to region where the operator is headquartered, proxy of its area of operation, only the coefficient estimated for the Central-West Region was statistically significant ($p < 0,01$). Operators based in this region spent, on average, 41.0% more than businesses located in the Southeastern region, which formed the reference group.

As for the influence of economic factors on healthcare spending, a positive association with the real GDP per capita growth statistically significant to 10% was demonstrated. An elasticity of 0.24 was estimated, i.e., for each 1.00% of GDP growth per capita there was an increase of 0.24% in healthcare spending.



4. Discussion

According to the results presented, between 2003 and 2013, the true impact on expenditure per capita of health plan operators, resulting from successive revisions to the List of Health Procedures and Events, was nearly 20%, which is significant when compared to the actual adjustment applied to the monthly fees of individual/family plans for the same period, at approximately 30%⁸. It is worth noting that, beyond the expansion of mandatory coverage, the readjustments of pecuniary compensation should also reflect inflation in the healthcare sector, which is usually higher than the general inflation rate, and the increased use of healthcare services seen in the context of the demographic and epidemiological transition, as highlighted by CARNEIRO and collaborators (2013).

Analyzing the effect of each Normative individually, it was found that RN No. 82/2004 made the largest contribution to increased expenditure on the part of healthcare operators. Whereas the resolution aimed to encourage the use of the List by performing logical adjustments to the previous instrument, it was found that these may have been more effective in increasing access to health services.

RN No. 167/2008 had the least impact on expenditure and this may be related to the nature of the procedures incorporated, which are mostly outpatient attendances, queries and non-medical sessions and these are usually less expensive than some types of diagnostic tests or procedures performed under hospitalization. The effect estimated by the model, of 2%, fell short of that estimated by agents of the regulated market, which, at the time of the release of the new list, claimed that healthcare spending would grow between 4 and 5% (AKL, 2011).

Conversely, the impact of 7% attributed to RN No. 211/2010, was slightly higher than the estimate released by the representatives of the operators, who estimated a spending increase in the order of 5% (AKL, 2011). Both estimates, however, are far higher than that of the ANS, which, upon review of the List, expected the growth of healthcare expenditure to be no higher than 1% (CESCHIN, 2011). It is suggested, therefore, that the cost of compliance imposed on operators by healthcare regulation over the last decade may have been underestimated by the ANS.

In relation to the structural characteristics of the health plan operators, it was found that the modality was the main factor associated with the healthcare spending per capita, which is substantially higher among insurers that specialize in health, whose average costs per procedure tend to be greater due to reimbursement of expenses incurred by the free choice of providers. Furthermore, the higher expense differential in relation to philanthropic and group medical can be explained, in part, by the reduction of costs through the vertical integration of services, a common feature between operators established under these two modalities, yet absent among insurers (ALVES, 2009).

⁸ Available at: <http://www.ans.gov.br/planos-de-saude-e-operadoras/espaco-do-consumidor/reajustes-de-precos-de-planos-de-saude/historico-de-reajuste-por-variacao-de-custo-pessoa-fisica>. Accessed on: 15 November, 2014.



Another important result evidenced by the statistical model was the negative association between the size of the operator and the healthcare spending per capita, which corroborates with the findings of ALVES (2008), who showed that the major operators, because they benefit from economies of scales, tend to be more efficient. Hence, as the author concludes, this difference should be considered by the ANS when drafting new regulations, since rules imposed linearly to all operators can penalise smaller operators to a greater degree.

In fact, as noted by OCKÉ-REIS (2006), the difficulty of controlling costs among the smaller operators has contributed substantially to the wave of mergers and acquisitions observed since the beginning of this century and, consequently, to the increased level of market concentration at the regional level.

5. Conclusion

The object of this work was to assess the impact on the healthcare expenditure of private health plans resulting from expansions made to the List of Health Procedures and Events, between the years 2003 and 2013, through the estimation of an econometric model with data panels. From the results presented, we conclude that this impact was significant and possibly higher than projected by the ANS.

It should be emphasized, however, that these results do not permit inferences about the quality of healthcare regulation developed by the ANS, since the social benefits resulting from the expansion of the minimum mandatory coverage List are not assessed.

One of the limitations of the study was the inability to break down the analysis by time (before or after the Law 9656/1998) and type of employment (individual or collective) for the healthcare plan because the level of aggregation of the data available. Furthermore, also due to the unavailability of data, it was not possible to insert demographic factors into the model, usually described as determining factors of the evolution of welfare spending, such as the age composition of beneficiaries.

In spite of its limitations, the results of the study point to the importance of the ANS moving forward in the implementation of quantitative methodologies of Regulatory Impact Analysis, such as cost-benefit and cost-effectiveness analyses, to support the decision for incorporation of new health technologies. As seen, the resistance to the use of RIA methodologies may contribute to market concentration and the increase of prices, resulting from increased costs for the entities being regulated and, consequently, to the exclusion of a portion of the plans from the healthcare market, in a way that is contrary to the objective of increasing access to healthcare goods and services.



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