WOULD THE REGULATORY FRAMEWORK PROPOSED BY THE HEALTH AND SOCIAL CARE ACT 2012 BECOME MORE EFFECTIVE IF IT USED THE BEST PRACTICES OF THE BRAZILIAN REGULATORY MODEL?

IVANDRO AGUIAR CAMPOS

Dissertation submitted in partial fulfilment of the requirements of
The University of Salford for the degree of
Master of Laws in Health Care Law

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Supervisor: Professor Parveen Tamadon-Nejad

LLM in Health Care Law Dissertation December 2012
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Initially, I would like to thank God for this new Victory.

This dissertation could not have been written without the generous support of the Brazilian Regulatory Agency named ‘ANS’, a government body created with a view to regulating health care plans companies. I am honoured to be part of this team.

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Authorship Declaration

Submitted by: Ivandro Aguiar Campos

I certify that all the material in this paper which is not my own work has been identified and acknowledged and that no material is included for which a degree has been previously conferred upon me.

I certify that the number of words in this paper does not exceed the maximum of 15,000 words excluding footnotes.

I understand that work of excessive length may be penalised.

Signature: ________________________________

Date: December, 12th 2012 ____________________

NAME (BLOCK CAPITALS): IVANDRO AGUIAR CAMPOS
This study sets out to demonstrate that it would be possible to enhance health care regulation in the United Kingdom by learning from the best practices of the Brazilian model for economic regulation in health care, which, in Brazil, has been applied successfully for 12 years, namely ever since the creation of the Regulatory Agency named ‘ANS’. This model of regulation – new in the UK - has proved to be very effective in Brazil, because patients’ needs and expectations are being more fully met by health plans companies.

The British government’s proposed approach to strengthening sector regulation in health care (which was set out in Part 3 of the new Health and Social Care Act 2012) will be discussed in some depth, as well as the specific framework of rules designed with a view to driving substantial improvements in health outcomes and quality of care.

This dissertation will debate the relationships between two different regulatory approaches with some similarities in the health care sector, as for example, the existence of a failure regime (a regulatory intervention created to ensure that patients do not lose access to essential services if a provider/health plans company runs into financial difficulty). The study will suggest ways to improve the use of economic regulation mechanisms by the British National Health Service (NHS).

Regarding the healthcare sector, the last three years have been crucial for the UK because a start has been made on designing a model of economic regulation. It all started in 2010, when the Government published a new White Paper named ‘Equity and Excellence: Liberating the NHS’. It is paramount that the decisions about this new regulatory design are properly informed by theoretical and practical understanding of the processes of regulation. Thus, the findings of this research will be used to show that the methods used by the Brazilian Regulator might well be successfully applied by the British Economic Regulator - Monitor.

**Keywords:** Health care; economic regulation; patients’ needs; Health and Social Care Act 2012; failure regime; National Health Service (NHS).
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CHAPTER 1

INTRODUCTION

Initially, it is worth highlighting the research question: How the new model of Economic Regulation for the Health Care Sector (which was set out in Part 3 of the Health and Social Care Act 2012) could improve in order to protect the patients’ interests? This dissertation seeks to take a dispassionate look at the potential lessons for the development of economic regulation in health care in the UK that can be learned from the Brazilian Experience. In Brazil the healthcare services are provided by the Government (Universal System) and by a strong private market represented by the health care plans Companies and Medical Insurers.

Beginning from an historical overview, the research starts by making a brief review of the legal framework supporting the powers and duties of different bodies within the National Health Service (NHS), such as the Department of Health, Monitor, NHS Trust Development Authority, NHS Commissioning Board and Care Quality Commission as examples within the UK system. The law underpinning the current public health care system will be discussed in Chapter 2.

In Chapter 3 the government’s proposed approach to strengthening sector regulation will be discussed in some depth. It is expected that regulation will help mitigate the problems related to limited access to services, high prices, perverse incentives and lack of information; as well as ensuring the safety and quality of healthcare services\(^1\). The new roles of Monitor and Care Quality Commission shall be debated too. The research will then analyse if this new regulatory model is an example of deterrence, compliance or responsive regulation.

As for Brazil, in Chapter 4 the performance improvement in health care system will be analysed before and after the introduction of economic regulation. A specific topic will present the intervention methods (inspection regimes) used by the Brazilian Regulatory Agency (which has the acronym in Portuguese of ‘ANS’) with a view to persuading the regulated organizations to improve their performance. Brazilian experience with the regulatory tool named ‘Regulatory Impact Analysis’ will also be commented on. Finally, the benefits to patients created after introducing economic regulation in the health sector will be discussed, emphasizing the key role of the Regulatory Authority.

The research for this dissertation will be desk-based and quantitative in nature. Its main focus will be on primary and secondary sources from both Countries, consisting of statute law, regulations, government policy documents, publications from regulators, books, journal articles and websites. The comments will be based on statistics and empirical data collected mostly from Government’s and Regulator’s Reports (usually macro-level regulatory interventions). The methodology adopted will certainly present some limitations because the regulatory interventions in both systems usually do not focus on the complexities and subtleties of individual organisational behaviour. However, this research methodology will outline the ‘big picture’ which will enable the reader to understand the incentives and enforcement strategies used by the UK and Brazil in order to create a more effective regulatory model.
CHAPTER 2
HEALTH CARE REGULATION IN THE UNITED KINGDOM

2.1 The British Scenario

In the UK, ever since the Tudor period, local authorities have regulated a wide range of issues. Local justices, for example, controlled the prices that could be charged for some products. With industrialization, a new structure of local government and authorities assumed regulatory responsibilities that included controlling development, planning, consumer protection and environmental health\(^2\).

Regarding the provision of healthcare services, a landmark event in the history of the United Kingdom was the creation of the National Health Service (NHS) in 1948, which was brought into existence by the provisions of the National Health Service Act 1946.

Prior to this, Stacey highlighted that free medical treatment was hardly ever available to the poor who depended largely on the charity of doctors and other philanthropists for treatment. One philanthropist in particular, William Marsden, founded the London General Institution for the Gratuitous Cure of Malignant Diseases in 1828. This was, in effect a hospital, where the only prerequisites for treatment were to have a disease and to be poor. Free treatment was provided to any poor or sick person who needed it\(^3\).

The Royal Free Hospital (as it was later known) soon became the victim of its own success. Demand for its services reached such a level that, by 1920, it was on the brink of bankruptcy. This forced the hospital to ask its patients to pay whatever they could afford towards their treatment thus ending the provision of free treatment.

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The NHS was then created in order to provide consistent levels of care, available to all citizens according to their needs. Since its beginning the paucity of resources has been the biggest obstacle to achieving these goals, mainly because there had been a gross underestimation of how much it would cost to run the NHS on a daily basis\(^4\).

The resource issue was just one of many problems which began to emerge as the NHS continued to develop. The tripartite structure of the NHS (separated as it was into care provided by hospitals, general practice and local health authorities) made it difficult to provide integrated care (as there was little co-operation between the three groups) and there were inevitable problems with administering the types of care provided by each of these groups as each was guided by its own philosophy and, accordingly had its own priorities\(^5\).

The solution to these problems was outlined by the Porritt Committee. This Committee recommended that the various different health authorities should be brought together and placed under the control of Area Boards. These recommendations were not implemented until the enactment of the National Health Service Reorganisation Act 1973 (NHSRA 1973), which came into effect on 1st April 1974. The aims of the Act were straightforward enough, namely\(^6\):

a) To unify health services;

b) To ensure a better coordination of care between health authorities and related local government services; and

c) To improve the management of the services provided under the NHS.

The re-organization effected by the NHSRA 1973 saw the introduction of 14 Regional Health Authorities (RHAs) which were to be responsible for the planning of local health care services. Beneath the RHAs were 90 Area Health Authorities (AHAs) which also had planning and management responsibilities and, importantly, also had responsibility for developing joint services with the local authority. Most of the areas governed by AHAs

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were further divided into districts which were represented the lowest tier of the Health Service.

The new levels of decision-making introduced by reorganizing the NHS were said to lead to unnecessary delays and too much bureaucracy. The Royal Commission reviewed some of the criticisms levelled at this new structure and reached the conclusion that there was one tier of administration too many in the new structure: in a nutshell - too many administrators.

The then Conservative Government responded to the findings of the Royal Commission’s report with a consultation paper entitled ‘Putting Patients First’ which recommended the introduction of District Health Authorities that would bring together the functions of the existing Area and District Health Authorities. This consultation paper led to the introduction of the Health Services Act 1980.

It is of paramount importance to highlight the most significant development in the 80’s: the publication of the Griffiths Report. The report suggested that the lack of clearly defined management functions was the major weakness of the NHS, which led to an inefficient use of resources and a failure to meet patients’ needs.\(^7\)

Despite these reforms, the decade saw a major financial crisis. Funding, provided by the government, was consistently falling below that needed to satisfy the increased levels of demand being put on the service. The Kings Fund Institute reported in 1988 that expenditure within the NHS was £400 million below its target level.

The major result of this was the decision of the then Prime Minister, Margaret Thatcher, to set up a review of the NHS. The group consisted of a team of ministers and chaired by the Prime Minister herself. The outcome was the White Paper ‘Working for Patients’ which set out, amongst other things, the Government’s proposals on how the delivery of health care could be improved. Rather than focusing on a need for greater

funding within the NHS, the focus was on making the service more efficient (i.e. cost effective). The basic idea was that competition between various providers of services could be used to drive up the efficiency and quality of services.

‘Working for Patients’ recommended the creation of something called the ‘internal market’. This mechanism created a split between those who ‘provided’ healthcare and those who ‘purchased’ it. Health Authorities were required to carry out an assessment of local health care needs, create strategic plans to identify how these needs could be met and then purchase services from NHS Trusts to fulfil these needs. The Health Authorities were also expected to monitor the quality of the health care that was provided. The relationship between purchasers and providers was to be governed by service agreements\(^8\).

Essentially these reforms were geared towards introducing the principles of the free-market into the NHS. Ham asserted that the underlying idea was that the increased competition for the ‘business’ of the Health Authorities would give the NHS Trusts (created under the terms of the reform) a stronger incentive for ensuring that they offered the highest quality and most cost-effective services\(^9\).

The changes recommended by ‘Working for Patients’ were implemented by the provisions of the National Health Service and Community Care Act 1990 (‘NHSCCA 1990’). This Act led to reforms of RHAs, DHAs and Family Practitioner Committees which became Family Health Service Authorities (‘FHSAs’) and differed from previous reforms brought about by statute in two main ways:

a) the changes were to be implemented gradually over time (not at once);

b) the Act did not contain a vast amount of detail on how these changes were to be implemented. It merely introduced a broad framework within which the NHS had to operate in order to implement the reforms.

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\(^8\) Shaun D Pattinson, Medical Law and Ethics (London: Sweet & Maxwell, 3\(^{rd}\) edn 2003) 29.

The election of the Labour Government in 1997 also impacted the NHS. The White Paper ‘The New NHS, Modern Dependable’ outlined Labour’s ‘Third Way’ for running the NHS. This would involve implementing a system which embraced those aspects of previous reforms which worked, whilst discarding those that did not, and which was based on partnership and driven by performance\textsuperscript{10}. The ‘internal market’ was to be abolished in favour of integrated care; however, its essence was retained. The White Paper included a commitment to maintain “the separation between the planning of hospital care and its provision” as the value of the strategic approach to planning health care delivery was clearly recognized.

Developments in the provision of health care within the NHS were to be guided by patients’ needs and the drive for openness and quality. This latter aim was to be achieved through a variety of approaches, the first of which was to create National Service Frameworks (‘NSFs’). These NSFs were to be developed by the Department of Health (‘DoH’) and were intended to improve standards of care across the NHS by providing detailed guidance on the level of care required within a defined service or the level of care that needed to be given during the treatment of a defined group. The NSFs would also include guidance on implementation strategies and set out performance indicators against which the new recommendations could be measured.

The White Paper also recommended the creation of the Commission for Health Improvement, which would eventually have responsibility for monitoring progress as a result of implementing the National Service Frameworks and corporate governance arrangements.

Further mechanisms proposed so as to help ensure the quality of care in the NHS were: to create the National Institute for Clinical Excellence (NICE), including explicit standards on quality in the newly created, long-term service agreements; to introduce

\textsuperscript{10} Department of Health \textit{The New NHS: Modern, Dependable}. (London: DoH, 1997)
National Patient Surveys (to determine public expectations of the service); to create of a new NHS Charter; and to introduce the concept of clinical governance.

The Department of Health was to shift its focus towards developing policy at a national level. It was also to be given responsibility for taking government policy on health and social services on board and to set a national framework which would have to be followed by NHS Bodies at the local level.

Kennedy\textsuperscript{11} stated that two major events occurred in 1998: the first was the celebration of the 50th Anniversary of the NHS; and the second, which rather overshadowed the first, was the revelation of the events which led to the death of Joshua Loveday at the Bristol Royal Infirmary, which would have major implications for future reforms of the NHS.

In this period, the paucity of resources continued to be a huge issue for the NHS. The Comprehensive Spending Review completed in 1998 led to a commitment to spend a further £21 billion pounds on the NHS between 1999 and 2002 and it was expected that this money would mainly be used to reduce waiting lists as promised by the Labour Government in their election Manifesto. However, a commitment to meet the principles set out in ‘The New NHS: Modern, Dependable’ along with pay increases promised to NHS staff soon eroded the amount of actual extra funding available.

Both the then Prime Minister (Tony Blair) and the then Chancellor of the Exchequer (Gordon Brown) recognized that there was a need to further increase spending on the NHS. This led to creating Modernization Action Teams which were given the task of trying to identify the major challenges facing the NHS and to come up with proposals for addressing these problems. The views of the Modernization Action Teams, Ministers and the Department of Health were collated and published in ‘The NHS Plan: A Plan for Investment, a Plan for Reform’ in July 2000\textsuperscript{12}.

\textsuperscript{11} I Kennedy  \textit{Bristol Royal Infirmary Inquiry: Learning from Bristol} (London: The Stationery Office, 2001)
The Department of Health received central responsibility for setting national standards of care and a more active role in ensuring that these standards were being met. The national priorities were to be set in three ways\textsuperscript{13}: a) development of further National Service Frameworks; b) NICE was to be given responsibility for appraising different forms of treatment and interventions and then, as a result of these appraisals, for providing clear guidance on which of those work best for patients; c) the Department of Health would also have responsibility for setting a small number of ‘ambitious but achievable’ national targets governing standards of care and efficiency.

According to the Plan, data was to play a major role in facilitating the monitoring of standards across the NHS. Performance Assessment Frameworks (‘PAFs’) were already in place to help assess the performance of Health Authorities, but further PAFs had to be developed for all NHS Trusts and Primary Care Trusts providing community services. These figures would have a real impact on the development and delivery of services within the organizations affected as the performance of the best performing services were to become the benchmark standards for the rest. It was the perfect environment for the advent of economic regulation.

\section*{2.2 The Rise of Economic Regulation}

It must be recalled that the need for a system of regulation on quality and safety was recognized in the Labour government’s first White Paper on health. At that time there was no national policy covering the relevant aspects of the quality and safety of health care provision. The senior researchers Maybin & Harrison from the King’s Fund\textsuperscript{14} highlighted that the Government addressed these issues by setting targets, such as those for waiting times, requiring trusts to introduce clinical governance systems and introducing a Performance Assessment Framework, which covered both quality and efficiency in service delivery. A new non-Departmental public body, the Commission for Health Improvement (CHI), was established by

\textsuperscript{13} T. H. S. Dent and M. Sadler, ‘From Guidance to Practice: why NICE is not enough’ (2002) 324 British Medical Journal 842

\textsuperscript{14} Jo Maybin and Tony Harrison, Regulation of Health Care Provision in England: Briefing (London: The King’s Fund; 2011)
the Health Act 1999, primarily to offer guidance to NHS providers in England and Wales on developing clinical governance.

The ‘NHS Plan: A Plan for Investment, a Plan for Reform’ encouraged the creation of a regular inspection regime for every NHS organisation. This was to be carried out every four years by the Commission for Health Improvement (‘CHI’) (with the support of the Audit Commission), although those who were identified as performing poorly would be subject to more regular (biennial) inspections.15

The institutions with the best performance would be rewarded with greater autonomy (including fewer inspections from CHI and a greater ability to control how funds were allocated at a local level) as well as access to further funds. On the other hand, poorly performing organisations were to be subject to closer scrutiny. The table below will demonstrate how the CHI addressed the significant failures found in the NHS Organisations.

<table>
<thead>
<tr>
<th>Areas of Concern</th>
<th>Regulator’s Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Performance of NHS Organisations</td>
<td>Inspection Regime</td>
</tr>
<tr>
<td>Where significant failings are found in the NHS Organisations during the inspection regimes, the CHI recommends special measures</td>
<td>Commission for Health Improvement (‘CHI’) (with the support of the Audit Commission and of the Modernization Agency).</td>
</tr>
</tbody>
</table>

In order to remedy the failings:

- Recovery Plan: the Organisations are encouraged to present a recovery plan to correct the care quality failings pointed out by CHI
- Replacement of the Management Team: in order to correct the failings found in management controls

Given its impact on recent developments in the health care service, the Plan’s recommendations were specific to accepting the patient at the heart of the service. At a superficial level, steps had to be taken to ensure that patients were better informed about the health service and the quality and variety of care they could expect.

Great importance was placed on improving the levels of protection available to the patient. In particular the Government was keen to point out the need for reforms in the way that professional regulatory bodies (such as the General Medical Council or the Nursing and

Midwifery Council) carried out their activities. The need to ensure a consistency of standards amongst the various regulatory bodies was recognised and a solution to that issue was put forward in the form of the UK Council of Health Regulators.

In 2004 a very important policy document was published: ‘Creating a Patient Led NHS: Delivering the NHS Improvement Plan’. Its main recommendation was to develop ‘a new framework of standards, skills, organisations, systems and incentives’. After all the reforms in the NHS outlined above, the system presented three types of bodies: those with strategic roles, those who commission services and those who provide services. The table below will summarise these bodies’ functions.

<table>
<thead>
<tr>
<th>NHS Bodies with Strategic Roles</th>
<th>NHS Bodies with Commissioning Responsibilities</th>
<th>NHS Bodies with Responsibility for Providing Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department of Health (DoH): sets national policy and overall direction in relation to health and social services. DoH also has responsibility for securing and distributing resources and for answering to Parliament about NHS performance.</td>
<td>Primary Care Trusts (PCTs): identify the health care needs and devise ‘local delivery plans’ for three years. PCTs are also responsible for commissioning services to meet local needs: a) Primary Care Services: general medical service agreements with General Practitioners (GPs), pharmacists and dentists; b) Second Care Services: second care providers (Trusts or private hospitals); c) Tertiary Services (Specialist e.g. cancer or diabetes services).</td>
<td>Primary Care: normally viewed as any healthcare service that is provided outside of a hospital setting. GPs control access to secondary care services through referrals. They are independent contractors that provide services under a contract to their PCTs.</td>
</tr>
<tr>
<td>Strategic Health Authorities (SHAs): implementation of strategic guidance at ground level. They oversee the planning and development of health care services in their area and are responsible for performance managing of the NHS organisations through accountability agreements.</td>
<td></td>
<td>NHS Hospitals were established as Trusts under the provisions of the NHS and Community Care Act 1990. They provide both emergency (acute) and planned (elective) secondary care services and make most of their money by selling their services to PCTs and to Practice Based Commissioners (PBCs).</td>
</tr>
<tr>
<td>At Arm’s Length Bodies (AALBs) - carry out particular functions on behalf of DoH: a) MONITOR is the independent regulator for Foundation Trusts (FTs). They grant licenses to FTs to operate and monitor them to ensure that they are complying with the terms of the license; b) National Patient Safety Association; c) NHS Litigation Authority; d) National Institute for Healthcare Excellence (NICE); Commission for Healthcare Audit and Inspection.</td>
<td></td>
<td>Foundation Trusts have to ask the permission of the Secretary of State for Health to apply for Foundation status, and the license to operate is granted by MONITOR under ‘terms of authorisation’.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Treatment Centres are ‘stand alone’ providers and PCTs may purchase services from them separately. They carry out elective procedures and specialise in dealing with day cases and short stay cases. The main focus tends to be high volume and low risk procedures.</td>
</tr>
</tbody>
</table>
It is worth mentioning that, in addition to being regulated for quality and safety, NHS organisations are subject to a set of financial rules. In recent years, these rules and regulations have been developed to allow some providers greater independence from central government and to actively encourage the better use of resources by NHS bodies.

According to Samanta and Samanta the access to capital was controlled by the Department of Health, and all major schemes had to have central government approval. The Audit Commission was responsible for ensuring trusts’ accounts were audited and any failings drawn to the attention of the Trust Board. In the first instance, the Boards were responsible for ensuring the financial stability of each Trust\textsuperscript{16}. Financial performance was monitored by health authorities. Essentially the same regime continued up to and after publication of the NHS Plan in 2000. The key indicator of financial performance remained achievement of break-even.

In the next sections, the regulatory roles of two relevant NHS bodies will be commented on, namely, Monitor and the Care Quality Commission.

2.3 The introduction of Monitor

As it was mentioned on the Table above, initially, MONITOR was designed to be the independent regulator for Foundation Trusts (FTs), granting operation licenses and ensuring their compliance with the terms of the license.

According to Maybin and Harrison, the creation of Foundation Trusts from April 2004 had a huge impact on the system of accountability\textsuperscript{17}. These two researchers from the King’s Fund Institute highlighted the fact that Foundation trusts have a kind of ‘financial freedom’. Thus, they are allowed to build up surpluses that can then be used for service development – and as a result do not need to balance their books on a year-to-year basis.

\textsuperscript{17} Jo Maybin and Tony Harrison, Regulation of Health Care Provision in England: Briefing (London: The King’s Fund; 2011) 8.
The requirements to become a Foundation Trust are, namely:

a) NHS trusts must demonstrate their ability to manage their finances effectively;

b) they must conform to a compliance regime set by Monitor. This body assigns a risk score to each trust and varies the intensity of its monitoring accordingly;

c) they must follow the terms of authorisation, which include stipulations about the maximum amount of money a trust can earn through private income.

2.4 The establishment of the Care Quality Commission

The Care Quality Commission (CQC) became the new health and social care regulator for England pursuant to the Health and Social Care Act 2008. It took over the roles of the Commission for Social Care Inspection, the Healthcare Commission and the Mental Health Commission. The goal of this entity is to ensure essential quality and safety standards, to drive improvement and to stamp out bad practice.

Since April 2010, all providers of health care in England, including NHS providers, foundation trusts and independent providers are legally bound to be registered with the CQC in order to provide services. The next section very briefly discusses the perspectives of the new NHS reform proposed by the Coalition Government as set out in a new White Paper.

2.5 White Paper ‘Equity and Excellence: Liberating the NHS (2010)’

The Government published a new White Paper on July 12th 2010 named ‘Equity and Excellence: Liberating the NHS’. This White Paper described a framework of reforms aimed at putting patients at the heart of the system, focusing on improving outcomes and empowering local organisations and professionals.
The next step taken by the Government was to introduce a Health and Social Care Bill in Parliament in January 2011. This document set out legislative changes to underpin the reforms and create a clear and stable legal regime. Following agreement by both Houses on the text of the Bill, it received Royal Assent on March 27th 2012. This new legislation focuses on five key areas:

a) it establishes an independent NHS Board to allocate resources and provide commissioning guidance;
b) it increases General Practioners’ powers to commission services on behalf of their patients;
c) it strengthens the role of the Care Quality Commission;
d) it transforms Monitor into an economic regulator to oversee aspects of access and competition in the NHS;
e) it abolishes Primary Care Trusts and Strategic Health Authorities.\(^{18}\)

2.6 Partial Conclusions

In the UK, which is close to a wholly state-funded and provided health care system, the tradition was not to use regulation to constrain the health care market. Instead, it was used to replace direct state ownership and government management of health care provision with a more distanced form of state control. However, the health care sector is dynamic and complex. The NHS became more diverse since a variety of commercial and not-for-profit entities were involved in the provision of health care services, and these new entities began to grow away from the Department of Health. These changes required new mechanisms to sustain accountability.

The next chapter comments on the rationale for economic regulation in the NHS.

CHAPTER 3
THE SHIFT TOWARDS A NEW REGULATORY ENVIRONMENT

This chapter will present the reasons and strategies presented by the UK Government for sector regulation in the NHS with a view to driving substantial improvements in health outcomes, quality of care and productivity to: care for an ageing population, manage the increased prevalence of chronic disease and manage the rising cost of healthcare technologies (such as new drugs and equipment).

The explanation will start with the rise of Economic Regulation in the NHS.

3.1 The Birth of Economic Regulation in the NHS

It must be recalled that the Labour government – which initially rejected a market in health care when first elected in 1997 - gradually returned to market-based approaches in the belief that centrally directed policies were not sufficient to drive the necessary improvements in performance.

Lewis et al stressed that in order to establish a level playing field between public and private providers, a new economic regulatory role would be needed to monitor and enforce appropriate competition, including ‘ex post monitoring of apparent abuse of dominant position and ex ante consideration of proposed mergers with respect to their impact on choice and competition within the market’.

The first model of independent regulation was then established, but the focus was on ensuring that all providers met minimum quality and safety standards (Care Quality Commission), and that the governance of foundation trusts was sufficiently robust to allow

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them to have greater operational autonomy (Monitor), rather than the focus being on competition.

In response to growing concerns that the introduction of a ‘real’ market in the NHS would lay the NHS open to challenge under European Union (EU) competition law, in 2008 the Department of Health published the Principles and Rules for Cooperation and Competition (Department of Health 2008), a set of rules designed to determine how the developing market should work. These guidelines covered mergers, anti-competitive conduct, misleading advertising and the procurement of NHS services.

In 2010 private sector providers complained that they were not being allowed fair access to contracts. The Co-operation and Competition Panel (created to examine these sort of complaints), confirmed that some primary care trusts were acting in a manner inconsistent with the principles and rules – they were limiting patient choice and restricting the ability of providers to offer routine elective services.  

Soon it became clear that the recommendations of the Co-operation and Competition Panel needed some kind of stronger legal backing in order to establish a stable regulatory framework, capable of sustaining accountability and meeting patients’ needs.

The next section discusses how the new Health and Social Care Act intends to establish this new regulatory approach by empowering patients to take more control of their care and through innovation in the way that healthcare services are delivered.

3.2 The New Roles of Monitor

The main purpose of the Health and Social Care Act 2012 was to introduce a system of independent economic regulation to sit alongside independent quality regulation. Aiming

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to move away from a system of top-down performance management, the rationale for economic regulation (to be carried out by Monitor) is to protect the public interest in the provision of services, particularly where communities are highly dependent on one provider, or very few providers\(^{21}\).

Since the inception of the NHS, small and specialist hospitals have been closed and their activities moved to larger units in the expectation that these larger units would offer better-quality, safer services at lower cost. This fact really happened in some parts of the country, such as in London and other conurbations, but in many areas, only one hospital that provides the full range of hospital services is within easy reach of the local population. Therefore, there is a public outcry if any of these are closed for cost-benefit reasons while if they are not, each holds a monopoly in its own area. In these areas, Dixon \textit{et al} argued that the position of Hospital Trusts is similar to that of the utilities before the break up of monopolies\(^{22}\). As with the utilities, there is always a risk of ‘exploitation’ through failure to improve performance in terms of quality and cost.

The Health and Social Care Act 2012 created new regulatory duties to Monitor, as follows: addressing anti-competitive conduct; responsibility to ensure the continuity of services and oversight of pricing and supporting the integration of services. These new regulatory responsibilities will be described in more detail in the following sections.

\textbf{3.2.1 Preventing Anti-Competitive Behaviour}

Based on the experiences of other countries and other sectors such as energy and water, Propper \textit{et al} asserted that this new regulatory approach is an attempt to address

\footnotesize
\begin{itemize}
  \item \(^{22}\) Anna Dixon, Tony Harrison and Claire Mundle \textit{Economic Regulation in Health Care – What can we learn from other regulators?} (London: The King’s Fund; 2011) 11.
\end{itemize}
potentially anticompetitive behaviour, through regulation where appropriate, rather than through costly legal proceedings.\textsuperscript{23}

Sections 72 and 73 (Chapter 2) of Part 3 of the Health and Social Care Act 2012 designed a new role for Monitor which is to prevent anti-competitive behaviour that is not in the interests of patients rather than for Monitor to positively encourage competition.

Patients and the public have consistently told the Government that they want more say and greater choice over their NHS healthcare. To address these claims this new function was designed. It is worth mentioning that a recent survey\textsuperscript{24} of 5,000 people that revealed that over 80 per cent of patients want more choice over how and where they are treated in the NHS and nearly three quarters of patients want more choice in who provides their hospital care.

\begin{itemize}
\item 81\% of respondents want more choice in where they are treated
\item 79\% of respondents want more choice in how they are treated
\item 75\% of respondents wanted a choice of hospital consultant in charge of their care
\item 75\% wanted a choice over which hospital consultant is in charge of their children’s care.
\end{itemize}

In this new scenario, Monitor will be able to carry out ‘market studies’ to investigate markets where competition is not functioning properly, for example because there are structural problems or other barriers to effective competition. It will also be able to advise Government and the NHS Commissioning Board on changes that would allow competition to function effectively.


\textsuperscript{24} Poll carried out the survey using a representative sample of 5,000 people in England. The fieldwork was carried out on 3 and 4 October 2011. The survey was commissioned as part of the Department of Health’s ongoing opinion research which seeks to understand people’s views and attitudes towards health and NHS issues.
The functions outlined above are concurrent with those that the Office of Fair Trading has under Part 1 of the Competition Act 1998, other than sections 31D(1) to (6), 38(1) to (6) and 51; and those that the Office of Fair Trading has under Part 4 of the Enterprise Act 2002 (market investigations), other than sections 166 and 171.

It is crucial to stress that in the healthcare sector, the new Health and Social Care Act enables Competition Law to be applied by Monitor, instead of reserving these matters for the Office of Fair Trading (OFT). And with regard to patients’ interests, this is a remarkable change, because the sector-specific regulator has the proper expertise to differentiate between where restrictions on competition have been acting against patients’ interests versus cases where there may be overriding benefits to patients of limiting competition, for instance, by concentrating specialist services in regional centres or in providing services through a clinical network.

3.2.2 Ensuring the Continuity of Services

Another of Monitor’s new functions which this research discusses is its duty to support the continuity of services by providing for a range of safeguards. The objective of these measures is to ensure that there is a smooth transfer if commissioners wish to replace existing services with better alternatives, or to ensure service continuity should a provider become insolvent (in this case Monitor will carry out the ‘Risk Regulation’).

Baldwin & Cave define risk as the probability that a particular adverse event will occur during a stated period of time, or result from a particular challenge. Monitor will undertake the monitoring of the performance of providers and Foundation Trusts by the routine collection, aggregation, comparison and analysis of performance data. In order to ensure the sustainability of services that meets patients’ needs, Monitor will maintain an assessment of risk and proactively intervene in response to distress. A clear framework was

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set out by the New Act to secure continued access to NHS services: Clauses 96 and 97 (Licensing), Chapter 5 (Health Administrations) and Chapter 6 (Financial Assistance).

This approach to regulatory detection is already used in Brazil with very good outcomes. The Brazilian Regulatory Authority (‘ANS’) carefully monitors the financial performance, as well as the quality of the health care services provided by health plan companies, through inspection regimes and intervention methods. The main advantage of this regulatory tool is to provide a highly focused and targeted review of performance in one area of the organisation, often with very specific recommendations for change or improvement. This issue will be commented on, in Chapter 3 in some depth.

Dixon, Harrison and Mundle draw attention to the fact that, historically, public providers have not been allowed to fail. The new Act has changed this tradition by introducing clearer arrangements for dealing with providers that are ‘financially unsustainable’. Enforcement powers were given to Monitor in order to intervene when a Foundation Trust is ‘in distress’, for example by appointing a turnaround team.\(^\text{26}\)

The previous government introduced a special administration regime to deal with insolvent trusts. The Health and Social Care Act 2012 strengthened this regime, and it also introduced new provisions that will apply to the private sector. Thus, the new legislation created stronger special administration arrangements in order to build additional protections to ensure the continued, safe provision of additionally regulated services in the exceptional event that a provider becomes insolvent. This regulatory intervention will have the task of providing an alternative to ordinary insolvency procedures under the provisions of Section 129 of the Act.

A key change is that Monitor will be able to intervene proactively to try to forestall potential failure and loss of continuity of service during a period of ‘distress’. It will have powers to trigger a ‘planning process’. Monitor will have to work closely with

commissioners and providers when a provider is ‘in distress’, and consult with a wide range of other stakeholders when drawing up plans for ensuring continuity of services in the event of a provider being unable to sustain services.

In the event that the provider cannot be rescued, then a continuity administrator will be appointed who will be responsible for recommendations on how to secure essential services as identified by the commissioners, under the provisions of Sections 134 and 162 (1)(4) of the Act. Monitor will be responsible for determining which of the options identified should be pursued. It will also have the power to raise finance through a levy on providers and purchasers to meet the costs of keeping the regime operational.

If a non-statutory provider becomes insolvent, existing corporate insolvency law will apply. However, if a non-statutory provider that supplies essential NHS services becomes unsustainable, a special administration regime for health companies will apply. These providers will have additional conditions attached to their licence from Monitor. The details of this will be set out in secondary legislation. This will, for example, protect patients or service users from a lack of continuity of access that would be to their detriment in the event of a major financial failure in a large provider such as Southern Cross.

3.2.3 Oversight of Pricing

This issue is a little complex and beyond the remit of the present study. However, brief remarks on it are necessary so that this study as a whole may be properly understood.

Up until the advent of the Health and Social Care Act 2012, the Secretary of State had been responsible for setting the prices for the healthcare sector on an annual basis. Nowadays, the Government has delegated this responsibility to the NHS Commissioning Board and Monitor. It was envisaged that these bodies could create a more stable environment with greater regulatory certainty so that providers would have the confidence to make long-term investments in services.
The new Health and Social Care Law states that the NHS Commissioning Board is responsible for specifying services and determining the currencies (units of services) that shall be used as the basis of pricing and payments. This provision took into account that it is the commissioners who are best placed to specify the currencies they need that will be aligned with service improvement. The new legislation also made Monitor responsible for developing the price methodology, thus aiming to create a more realistic and independent pricing process\textsuperscript{27}.

### 3.2.4 Supporting Integration of Services

The new legislation seeks to encourage and enable the delivery of integrated services, thus reducing inequalities for patients. The Commissioners will decide which tools are the most appropriate for each case. For some services and client groups (e.g. older people, end-of-life care, children with complex needs, the homeless, cancer care), highly integrated services would be likely to best meet patients’ and service users’ interests. In such cases, commissioners may decide to run a tender for a ‘prime contractor’ who would be responsible for providing effective care co-ordination and delivery.

For other circumstances, commissioners may decide that an effective way of driving-up quality (particularly of some, often neglected, community services) would be to introduce allowing the patient to choose Any Qualified Provider, with competition based on quality not on price.

The new legislation is very clear about the primacy of patients’ interests and in order to achieve this, the Act empowers Monitor with a wide range of functions, for example, supporting the NHS Commissioning Board in identifying and spreading good practice in the development of reimbursement systems; and in ensuring that incentives are optimised and aligned.

\textsuperscript{27} Department of Health \textit{Protecting and Promoting Patient’s Interests: the Role of Sector Regulation} (London: DoH, 2012) 32.
3.2.5 Joint Licensing

It is crucial to point out that Monitor will have powers to operate a licensing regime for providers of NHS services. This will be a key tool by which Monitor will influence the behaviour of NHS service providers in order to fulfil its duties.

A joint licence and registration regime for new providers will operate between Monitor and the Care Quality Commission under the provisions of Sections 86, 87 and 94 of the Act. Where a provider is required to be registered with the Care Quality Commission, having this registration in place would be a prerequisite for holding a licence. Once fully established, the joint licensing and registration process will offer a single integrated application to providers and require them to apply for both a licence and registration at the same time.

The new Act has also established that secondary legislation will empower the Secretary of State to determine exemptions from the requirement to be licensed, to ensure that the licensing regime is proportionate and targeted towards those parts of the healthcare system where it can achieve the greatest benefit. The Table below shows the proposed regulatory architecture:

<table>
<thead>
<tr>
<th>NHS Commissioning Board</th>
<th>MONITOR</th>
<th>Care Quality Commission</th>
</tr>
</thead>
<tbody>
<tr>
<td>Integration of Services</td>
<td>Joint Licensing</td>
<td>Joint Licensing</td>
</tr>
<tr>
<td></td>
<td>Licence</td>
<td>Registration</td>
</tr>
<tr>
<td></td>
<td>Address Anti-competitive Behaviour</td>
<td>Safety and Quality</td>
</tr>
<tr>
<td>Pricing</td>
<td>Pricing</td>
<td>Good Procurement</td>
</tr>
<tr>
<td>Continuity of Services</td>
<td>Good Procurement</td>
<td>Continuity of Services</td>
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<tr>
<td></td>
<td>Continuity of Services</td>
<td>Continuity of Services</td>
</tr>
<tr>
<td></td>
<td>Functions of Foundation Trust Regulator</td>
<td>Functions of Foundation Trust Regulator</td>
</tr>
</tbody>
</table>

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3.2.6 Duty to undertake Impact Assessments

The Health and Social Care Act 2012 has also highlighted the importance of the regulatory tool named ‘Impact Assessment’ on Section 69 1(a)(e). It states that Monitor is compelled to carry out impact assessments if the regulator is proposing to do something that it considers would be likely:

(a) to have a significant impact on people who provide health care services for the purposes of the NHS;
(b) on people who use health care services provided for the purposes of the NHS;
(c) on the general public in England; or
(d) to involve a major change in the activities Monitor carries on or in the standard conditions of licences.

Before implementing the proposal, Monitor must either carry out and publish an assessment of the likely impact of implementation, or publish a statement setting out its reasons for not doing so.

On September 8th 2011, the Department of Health published the Health and Social Care Bill 2011 - Coordinating Document for the Impact Assessments and Equality Analysis. This document intended to demonstrate the positive impacts caused by the proposed changes aiming to move the NHS towards a system that puts patients first, where there is a greater focus on outcomes, and where professionals and providers have the freedom to innovate and respond to patient needs and aspirations. 

3.3 The Regulatory Impact Analysis (RIA) – Concept

It is worth mentioning that the Document for the Impact Assessments and Equality Analysis mentioned above is a kind of Regulatory Impact Analysis (RIA), which is a regulatory tool from which decision makers can obtain useful information on the regulatory

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policy. The design of the RIA dates back to the British Utilitarian philosophers of the nineteenth century, especially Bentham. This regulatory tool was created with a view to improving the quality of the rules and increasing transparency.

Delia Rodrigo pointed out that new regulatory arrangements had to be carried out in order to catch up with technological innovations, consumer demand for better services, the evolution from manufacturing economies towards service ones, and interdependencies in regional and global markets. Thus, governments faced a transition to market-led growth to maintain economic performance. All these changes necessitated supply-side reforms that stimulated competition and reduced regulatory inefficiency.\textsuperscript{30}

To regulate better became paramount. Against such a background, the focus of regulation changed from identifying problem areas, advocating specific reforms and eliminating burdensome regulations, to a broader reform agenda that includes adopting a range of explicit, overarching policies, disciplines and tools. One of these tools – Regulatory Impact Analysis (RIA) - is a clear example of the trend towards more empirically-based regulation and decision-making process. Policy makers increasingly value regulation that produces the desired results as cost-effectively as possible. The next section discusses the British health care regulatory model.

3.4 Analysing the British Health Care Regulatory Model

Initially, it is worth mentioning that there are three regulatory models: deterrence, compliance and responsive regulation.

It is argued that deterrence regulators see the entities they regulate as ‘amoral calculators’, out to get what they can and only likely to comply with regulations if they are forced to do so. These regulators tend to adopt a punitive, adversarial approach to the regulatory task, and to make routine use of sanctions and penalties\textsuperscript{31}. On the other hand, compliance regulators see the organisations they regulate as ‘good-hearted compliers’ who

\textsuperscript{30} Delia Rodrigo, \textit{Regulatory Impact Analysis in OECD Countries – Challenges for Developing Countries} (Bangladesh: Organisation For Economic Co-Operation And Development, 2005) 2

will generally try to do the right thing. These regulators have a more supportive approach to the regulatory task and use formal penalties as a last resort.

In 1992, Ayres and Braithwaite created the term ‘Responsive’ Regulation, aiming to move beyond the longstanding and rather polarized debate between advocates of regulation and deregulation, and ideas of deterrence versus compliance. Responsive regulation is flexible, situationally specific, adaptable and can be characterized as being founded on six main concepts: contingency, hierarchy, flexibility, tripartism, parsimony and empowerment. Each of these will be defined in more detail below.

3.4.1 Contingency

Contingency is the core principle of responsive regulation. The idea is to make the nature of the regulatory regime highly contingent on the behaviour of individual regulated organisations. Thus, high-performing organisations are deliberately treated differently from low-performing organisations, and ‘amoral calculators’ are dealt with differently from ‘good-hearted compliers’. A contingent approach creates its own performance incentives, for instance, by giving greater regulatory freedom to high-performing organisations.

3.4.2 Hierarchy

The aim is to provide the regulator with a full suite of regulatory interventions that can be used responsively and tailored to the needs of individual regulated organisations. The interventions at the bottom of the pyramid are the more frequent ones and involve the least intervention. As the pyramid is ascended, the interventions become more significant, more expensive in time and are expected to be used on a smaller numbers of organisations. At the top of the pyramid are the ‘nuclear interventions’ that should be used very rarely (serious cases of poor performance).

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3.4.3 Flexibility

It has been argued that systems of regulation should be fair and consistent in their treatment of regulated organisations in such a way that every organisation can see how assessments are made and judgements are arrived at. However, this approach has some disadvantages, because highly prescriptive rules and standards leave little room for regulators to exercise discretion or judgement. Thus, the advocates of responsive regulation would assert that effective regulation should be flexible.

3.4.4 Tripartism

Another idea supported by the supporters of responsive regulation is that regulatory arrangements should be designed with a view to co-opting other stakeholders (with an interest in the regulated entity’s performance) for the purposes of regulation. Thus, the
approach called ‘Tripartism’ emphasises that the relationship between the regulatory authority and a regulated organisation is not simply bilateral, but there may be many other players involved in the regulatory process.

In the case of British health care regulatory model proposed by the new legislation, Monitor will have to work closely with commissioners and providers when a provider is ‘in distress’, and consult with a wide range of other stakeholders when drawing up plans for ensuring continuity of services in the event of a provider becoming unsustainable. So the idea of tripartism is absolutely clear and is supposed to be applied by the regulator.

3.4.5 Parsimony

It is argued that Regulatory regimes should be designed to use the least intrusive and cheapest possible regulatory interventions to achieve their objectives. Ayres and Braithwaite point out two reasons to promote a parsimonious approach: to minimise the costs of regulation to the regulator and to the regulated organisations; and to minimise the side-effects and unintended consequences of the regulatory methods and interventions.

Therefore, the concept of parsimony will be useful to decide what kind of regulatory regime is needed.

3.4.6 Empowerment

It has been argued that regulation should be designed to support improvement across the spectrum of performance, not just to set minimum standards which become accepted norms. In other words, regulators should aim to empower organisations to do well, rather than impose requirements that may constrain or limit what they do.

Walshe identifies two problems related to putting the empowerment concept into practice:\(^{34}\):

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1) Regulation should focus on the long-term goal of performance improvement, rather than the achievement of short-term regulatory objectives;

2) The likely benefits and drawbacks of regulatory intervention need to be assessed, taking into account their impact on all regulated organisations.

The author mentioned above asserts that sanctioning an organisation for a regulatory breach may force them into immediate compliance, but doing so also creates resentment that makes it less likely that they will be good regulated entities in the future. Another point to consider is that introducing a regulation that brings some improvement in a tiny proportion of entities at the cost of deterring innovation in many other regulated organisations should be avoided.

A clear example may be taken from Sections 72 and 73 (Chapter 2) of Part 3 of the Health and Social Care Act 2012, which designed a new role for Monitor with a view to preventing anti-competitive behaviour that is not in patients’ interests. It is paramount to bear in mind that although regulation can bring benefits by creating a system of fair competition and preventing abuse by providers that retain monopoly power, there is a risk that excessive regulation will stifle innovation and integration. Therefore, Monitor should adopt a facilitative approach, which encourages providers to take risks and innovate.

### 3.4.7 The British Health Care Regulatory Model

It should be remembered that the main purpose of the Health and Social Care Act 2012 was to introduce a system of independent economic regulation to sit alongside independent quality regulation. With the aim of moving away from a system of top-down performance management, the rationale for economic regulation (to be carried out by Monitor) is to protect the public interest in the provision of health care services.

It is worth mentioning that the financial pressures in the NHS were being felt particularly harshly by acute Hospital Trusts. A number of trusts and foundation trusts were being rated as at financial risk, and some trusts declared they were not financially
sustainable. In the past, the Department of Health bailed out unsustainable organisations. Under the new legislation, if Foundation Trusts are not able to balance their finances they will be declared ‘unsustainable’ and will go into administration (regulatory intervention). The rules that govern this process are often referred to as the ‘failure regime’, although the formal term used in government documents is still the ‘continuity of services framework’ as asserted by Harrison and Dixon\textsuperscript{35}

Even before the inception of the Health and Social Care Act 2012, it may be asserted that the British model of regulation tended to be more (but not completely) compliance-orientated and negotiated. However, after the advent of the new legislation, some characteristics of the responsive paradigm will also be present, such as ‘tripartism’. For example, Monitor will have to work in coordination with commissioners and other stakeholders when a provider is in ‘distress’ in order to establish the actions to be taken to ensure the continuity of health care services.

Dixon et al advocated that Monitor will need to have powers to exercise proactive financial oversight, particularly where providers have a certain level of market penetration. It will need access to information to enable it to assess the financial risks a provider faces, and powers to apply sanctions or require actions to be taken to limit these\textsuperscript{36}. These measures are a last resort, and it is important that, wherever possible, commissioners and providers work to plan service reconfigurations that avoid the need for intervention by Monitor.

One thing is absolutely clear: the reasons for establishing a failure regime are manifold. First, the government no longer wishes to bail out inefficient and unsustainable providers. In the past, hospital and other trusts incurred deficits, but these deficits were usually met from central funds to allow trusts to continue to provide services. The system for providing such financial support, and the criteria used were opaque and not subject to

\textsuperscript{35} Anna Dixon and Tony Harrison. \textit{Dealing with financially unsustainable providers – How will the failure regime work?} (London: The King’s Fund; 2012)

\textsuperscript{36} Anna Dixon, Tony Harrison and Claire Mundle \textit{Economic Regulation in Health Care – What can we learn from other regulators?} (London: The King’s Fund; 2011) 2.
effective external scrutiny, as stated by Palmer. By 2006, 190 NHS bodies had reported deficits, some for more than one year in a row. The Department of Health responded by requiring these bodies to draw up recovery plans, and a National Programme Office was established in 2006 to oversee the turnaround process. The total NHS budget was top-sliced to the tune of £450 million to fund these continuing deficits.

Harrison and Dixon have drawn attention to the fact that despite great efforts to reduce deficits, central funds have continued to be made available to cover deficits for some NHS trusts. As a result of the absence of clear rules about how to deal with persistent poor financial performance, there was no incentive for NHS trusts to tackle the problem. Resources that could otherwise be spent on higher quality care continued to be diverted to supporting financially unsustainable trusts. With the new Act, the government has made it clear that it no longer wishes to prop up inefficient services in this way.

In the 2009 Health Act, the Labour government introduced a failure regime to deal with those trusts unable to reach financial balance. However, this regime was not activated until 2012, when the current government announced that the South London Healthcare NHS Trust would be put into the unsustainable provider regime.

It is worth mentioning that a separate failure regime, building on that for NHS trusts, was introduced for Foundation Trusts in the Health and Social Care Act 2012. In addition, the Act set out a similar regime that will be applied to private sector providers of services to the NHS. In both instances, the main purpose of the Act’s provisions is to ensure that patients do not lose access to essential services if a provider runs into financial difficulty.

Another issue to be considered is that the regulator must guard against provider capture. This means balancing the voice of providers with those of patients and taxpayers. Monitor will also have to work closely with commissioners (as the agents of local

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38 Anna Dixon and Tony Harrison. *Dealing with financially unsustainable providers – How will the failure regime work?* (London: The King’s Fund; 2012)
taxpayers and patients) to ensure continuity of services. With a view to becoming more responsive to patients, the new legislation created an entity to represent them called HealthWatch, which will be discussed in the next section.

3.4.8 The Voice of the Patients - HealthWatch

The Health and Social Care Act 2012 proposes to give patients and the public a stronger voice, by evolving Local Involvement Networks (LINks) into local HealthWatch organisations, supported and led by HealthWatch England as an independent consumer champion within the Care Quality Commission.

It is expected that HealthWatch England will act as a consumer champion and learn from the experience of Consumer Focus to ensure that Monitor and the Care Quality Commission operate effectively in the interests of British people who need to use health care services. Therefore, Monitor needs to set out clear guidance for local HealthWatch groups to ensure that they are clear about their role as consumer advocates in their areas, promoting choice, and spotting patterns of complaints and local concerns that may require escalation to the regulator (regarding this issue, the Brazilian experience might be very usefully applied in the NHS).

3.5 Points to be fixed in the Regulatory Approach proposed by the Government for the NHS

It should be pointed out that there are also some controversial points about the NHS reforms.

Dixon et al argued that it is not clear whether it is the commissioners or Monitor who will ultimately shape the market in health services, so the government should clarify which of these scenarios it anticipates\textsuperscript{39}. This remains an inherent tension in the reform, and the outcome will partly depend on the balance between those services that are required to

\textsuperscript{39} Anna Dixon, Tony Harrison and Claire Mundle Economic Regulation in Health Care – What can we learn from other regulators? (London: The King’s Fund; 2011) 12.
be open to any qualified provider, and those that commissioners choose to award through a process of tendering.

Another potential problem is the risk of regulatory failure. There are huge challenges to overcome in the short term to enable Monitor to take up its new responsibilities effectively – for example, hiring sufficient staff with the skills and expertise needed. Technical challenges do exist as well, such as setting efficient prices that are not detrimental to quality, do not lead to the withdrawal of services, or risk making a lot of providers financially unsustainable. The lack of good information about the cost structures of hospital services and the absence of any cost information in other parts of the health system make this a hard task.

The last point to be stressed is that Monitor is likely to face intense political lobbying as a regulator given its role in ensuring continuity of services and the implications for local service configurations.

3.6 Partial Conclusions

This chapter described the shift towards a new regulatory environment in the British Health Care System. The economic regulator Monitor will need to develop a nuanced approach, balancing, on the one hand, its proactive intervention powers to remedy market failures and, on the other, its concurrent powers with the competition authorities. What is clear from this chapter is that regulation in the NHS will evolve i.e. it will take some time to develop.

The effectiveness of regulatory interventions needs to be carefully weighed against the harm caused by the market failures Monitor seeks to address. There are also significant costs involved in introducing economic regulation, as well as indirect costs to providers.

There is a consensus that to achieve the objectives outlined at the beginning of this chapter (to prompt substantial improvements in health outcomes, quality of care and productivity) an effective regulation in the NHS is extremely necessary. It is expected that
the introduction of economic regulation in the health care sector will be very helpful to ensure compliance with essential quality requirements, securing continuity of services and preventing abuses by powerful providers.

The next chapter will seek to demonstrate that it would be possible to enhance health care regulation in the United Kingdom by learning from the best practices of the Brazilian model for economic regulation in health care, which, in Brazil, has been applied successfully for 12 years, namely ever since the creation of the Regulatory Agency named ‘ANS’.
CHAPTER 4

HEALTH CARE REGULATION IN BRAZIL

The Brazilian private healthcare sector sprouted in São Paulo (the industrial heart of the country) in the 1960s. Automobile factories offered their employees access to private healthcare services through agreements with health service companies and providers.

According to Serra\(^{40}\), at the beginning, the sector had no regulation at all. Entry into the market was a free-for-all and the first healthcare service companies (which later became health plan companies and medical insurers) were started under a wide range of legal forms, such as: anonymous societies, limited liability companies, medical work cooperatives, philanthropic hospitals etc.

The Brazilian public healthcare system (known in Brazil by the acronym ‘SUS’) has the same problems as the British one: the paucity of resources has always been the biggest obstacle to providing consistent levels of care\(^{41}\). As a result, the private health plan market grew quickly. It is worth mentioning that, in the Brazilian context, the word ‘plan’ means a private healthcare service contract, through which the providers must offer medical services requested by users, who pay a premium or fee to the Medical Insurer or Healthcare Plan Company. The providers are contracted by the Medical Insurer or Healthcare Plan Company.

Until 1985, the plans commercialized were almost exclusively corporate ones. Contracts with private individuals only started to appear towards the end of the 1980s due to the massive entrance into this market of the largest medical insurers.

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According to the provisions of Article 5, item XXXII of the Brazilian Federal Constitution/1988, the rights of consumers of private medical insurers are classified in the special category of Fundamental Rights. Furthermore, protecting consumers is also an economic order principle, under the provisions of the Constitutional Law (Article 170, item V and Article 196).

Marques and Schmitt\textsuperscript{42} have highlighted the fact that a private healthcare service is an activity that seeks profit and it is the Government’s duty to impose ‘regulations, supervision and control’ of both health plans companies and the private healthcare contracts, which exhibit high public interest. Thus, the state carried out its duty to protect its citizens by creating the Supplementary Health National Agency – ‘ANS’, which has classical regulatory powers and is invested with the authority to protect consumers’ rights.

Data from ANS shows that in the year 2012 there were about 1,178 health plan companies in Brazil. Despite this huge number of firms being active for a long time, which should have improved the system by lowering prices while providing services of reasonable quality (in line with basic economic principles), this phenomenon did not happen in Brazil due to specific market imperfections, such as, solvency problems and abuses against consumers\textsuperscript{43}.

### 4.1 Solvency Issues

Before the introduction of regulation in the health sector in Brazil, competition between medical insurers and health plans companies was carried out without due regard being given to how prices should be set. At the beginning, many firms did not have appropriate financial and technical support As a result, if a competitor charged a price X, the firm would charge X – 1 regardless of the financial consequences of this practice.


\textsuperscript{43} Ministry of Health – Brazil – ‘Agência Nacional de Saúde Suplementar’ \textit{Foco Saúde Suplementar} (Rio de Janeiro: June 2012) 32
With respect to solvency issues, Mello (a Brazilian Supreme Court Minister) highlighted the importance of actuarial analysis, which is a calculation method born in the UK and used to verify if the health care costs are lower than the fees paid by the beneficiaries (patients)\(^4\). Once these costs are not easy to measure, a careful actuarial analysis will be necessary in order to obtain, with some reliability, the price to be charged by a health plan if it is to make a reasonable profit.

The Brazilian Regulatory Authority (‘ANS’) carefully monitors the financial performance, as well as the quality of the health care services provided by the companies, through inspection regimes and intervention methods. The table below shows how these regulatory tools work.

### Inspection Regimes and Intervention Methods used by Brazilian Regulatory Agency for Medical Insurers and Health Plans Companies

<table>
<thead>
<tr>
<th>Areas of Concern</th>
<th>Regulator’s Response Intervention Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of Healthcare Services</td>
<td>Care Quality Intervention</td>
</tr>
<tr>
<td>Solvency Problems</td>
<td>If the Care Quality Recovery Plan is not approved by the ANS Board of Directors,</td>
</tr>
</tbody>
</table>
<pre><code>                            | the regulatory authority will establish a special administration regime to ensure the |
                            | secure provision of healthcare services.                                           |
</code></pre>
<p>|                                   | Solvency Intervention                                                             |
|                                   | If the Solvency Recovery Plan is not approved by the ANS Board of Directors,       |
|                                   | the regulatory authority will establish a compliance regime to ensure the continued  |
|                                   | provision of healthcare services, building in additional financial protections to the |
|                                   | firms.                                                                             |</p>

Where significant failings are found in the firms during the inspections, Regulation Specialists recommend special measures in order to remedy the failings:

- **Recovery of Care Quality**: the firms are encouraged to present a recovery plan to correct the care quality failings pointed out by ANS Specialists
- **Recovery of Solvency**: the firms are encouraged to present a recovery plan to correct the failings found in the management and solvency controls

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These inspection regimes and intervention methods used by the Brazilian Regulatory Agency for Medical Insurers and Health Plan Companies (‘ANS’) have proved to be a successful enforcement strategy. These are compliance regimes with a view to ensuring the continuity of the provision of private healthcare services (named ‘prudential regulation’).

In order to build in additional forms of protection for patients, ‘ANS’ has defined all the rules for entry into (special license conditions), operation in and exit from the market. The basic goal of these regulations is to ensure that only those companies which have a strong financial capacity remain in the health care sector.\(^45\)

The solvency of a medical insurer corresponds to its ability to pay the claims. A health plan company is insolvent if its assets are not adequate (over indebtedness) or cannot be disposed of in time (illiquidity) to pay the providers. Thus, the prudential regulation focuses on the enforcement of financial disclosure through financial reports (which are regularly sent to the regulator), the requirement of minimal capital and the use of inspection regimes and intervention methods. These tools might well be used to enhance Monitor (the British Economic Regulator).

If the companies inspected do not take the specific actions required by ‘ANS’ within a specified time period (12 months), the regulatory agency will remove the company’s Board and declare a non-judicial settlement against the company.

A special administrator will be appointed by ‘ANS’ in order to commission all the providers and pay the company’s debts, by selling its assets. The beneficiaries of the company being liquidated will be transferred to another medical insurer or health plan company.

4.2 Consumers’ Complaints

Abuses against consumers committed by the firms are another example of market imperfection of the Health Plan sector. Refusing to provide a service, abusively readjusting fees, coverage exclusions, limiting periods of hospitalization, arbitrarily annulling contracts, lack of transparency etc are commonly reported by health plans’ beneficiaries to the regulatory authority.

‘ANS’ has a complaints procedure, which is followed by its Department of Inspections. Healthcare services must be responsive to the beneficiaries and when things go wrong, they have a right to have their complaints addressed in a fair and impartial way. This is another good practice, aspects of which the British body – HealthWatch England - are likely to find useful with regard to how to introduce and apply their own complaints procedures.

If the patient reports an example of undesirable health plan behaviour (for example, a refusal to commission a surgery requested by an elderly patient), it is the regulator’s duty to respond properly using enforcement strategies. If the company is found to be responsible for the problem detected, ‘ANS’ will impose heavy fines by means of an administrative process.

Moreira Neto highlighted that regulators can resort to administrative sanctions in dealing with companies and that these administrative measures can be provided for in statutes in Brazil. For example: administrative fines, improvement and prohibition notices which require remedial actions to be taken within a fixed period or which order the discontinuance of an irregular practice.
It is important to mention that it is possible, as laid down in the Health Plan Law (Law 9656/1998), under sections 29 and 29-A, that the regulator enters a kind of agreement with the company, called a ‘Commitment to Adjusting Conduct’, in order to prevent abusive practices against consumers and to improve the quality of healthcare services. This represents a more supportive approach to the regulatory task, with the use of formal penalties as a last resort (Compliance Regulatory Model).

Data from ‘ANS’ (year 2010) from the Pernambuco Inspection Department indicated that the main issues faced by patients were:

<table>
<thead>
<tr>
<th>Areas of Concern</th>
<th>Demand Occurrences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contracts (Annulment/non-fulfilment)</td>
<td>227</td>
</tr>
<tr>
<td>Price Readjustment</td>
<td>399</td>
</tr>
<tr>
<td>Coverage Exclusions</td>
<td>1,597</td>
</tr>
<tr>
<td>Pre-existing Illnesses</td>
<td>3</td>
</tr>
<tr>
<td>Reduction in the network of Providers</td>
<td>112</td>
</tr>
</tbody>
</table>

Limiting and excluding medical procedures (coverage) used to be justified not only because risks were selectively chosen, but also by inducing the demand offered by some providers. For example, in order to avoid raising their costs, companies used to establish limits to the provision of healthcare services49. For example, if a patient was hospitalized, the health plan firm would only pay for the first 30 days; if a physician ordered 10 tests in a month, the firm would only pay for the first 3 procedures. These practices have been severely punished by the regulatory authority (Deterrence Regulatory Model).

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4.3 Brazilian Regulatory Framework

Souto asserted that the Health Plan Market in Brazil, even after a long period of free competition, has not achieved reasonable levels of efficiency. As a result, public opinion has turned against health plan firms and medical insurers and has requested government intervention through regulation.


It is worth defining what a rulemaking process means. Rulemaking refers to the process that regulatory agencies use to create regulations. Legislatures rely on rulemaking to add more detailed technical and scientific expertise to a policy - fleshing out the broader mandates of authorizing legislation. In the modern Regulator State, legislatures often find areas where it is impractical for lawmakers to apply the level of detail or expertise required to establish complete standards. These they delegate to agencies for follow-up rulemaking.

In ‘ANS’ rules were created to cover five regulatory dimensions:

- Coverage offered by the Health Plan (product regulation);
- Licensing Companies (prudential regulation);
- Price and competition regulation;
- Assessment regulation;
- Compensation to the Public Healthcare System.

The prudential regulation has already been discussed. The product regulation will be commented on in the section below.

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4.3.1 Product Regulation

Product regulation is associated with the rules created with a view to minimising problems in the quality of care presented by health plans firms and medical insurers. It is worth remembering that the primary aim of the regulation is to reduce the practice of companies selecting risks and adopting other abusive mechanisms. Following this approach, ‘ANS’ created a number of new concepts\(^{52}\), such as:

a) **Pre-existing Conditions/Illnesses.** Regulation made it illegal to exclude procedures related to pre-existing illnesses after 24 months from the purchase of the healthcare services contract. Health plan firms are obliged to prove, through medical exams, that the consumer had the adverse medical condition before the purchase of the plan; otherwise, the consumer may not be excluded.

b) **Emergency/Urgency Procedures.** Emergency and urgency procedures must be covered as from 24 hours after the purchase of the plan (the Law defined as an emergency any situation that could cause the death of or permanent damage to the patient; urgency was defined as any risky situation caused by accidents or during pregnancy).

c) **Obstruction to Access.** No one can have their access to a health plan obstructed, irrespective of his/her age or medical condition. Although health plan companies cannot reject users, they still have the alternative of surcharging patients with pre-existing, adverse medical conditions.

d) **Substituting a Provider.** In order to exclude a provider from its network, the firm has to ask the regulator for clearance. The health plan must substitute it with another provider of a similar quality and communicate this to its beneficiaries.

In the next section, the first Brazilian experience with the regulatory tool named ‘Regulatory Impact Analysis’ will be discussed. It is worth remembering that this tool has been used in the UK for a long time.

4.3.2 Regulatory Impact Analysis

After listening to providers and patients’ groups (reported during some meetings and public hearings in 2011), the Brazilian Authority observed that on many occasions when a patient (the user of a Health Plan) tried to be admitted to a better standard of accommodation, when a bed was unavailable at the lower standard (in accordance with the terms of his/her contract) in the hospitals licensed by the health plans, neither the health plan nor the provider wished to pay the extra fee due for the admission of such a patient. Thus, a new approach to responsive regulation was necessary in order to extend the regulator’s oversight over regulated organisations, taking into account the views of all stakeholders, as pointed out by Campos and Souza\(^{53}\).

The regulatory intervention aimed to enforce the provisions of Article 33 from Brazilian Law 9656/1998 to ensure the patient the rights to a higher level of accommodation in the case of unavailability of beds at the lower level of accommodation (in accordance with the terms of his contract), with no additional burden to the patient. The purpose of the new rule was to clarify the obligation of the health plans to pay for the patient admission additional fee, because Brazilian Legislation did not indicate that clearly.

To cope with this problem, Brazilian Regulators used the Regulatory Impact Analysis (RIA) in the new rule creation process. It represents a mechanism for obtaining useful information for the decision makers concerning the regulatory policy. Co-opting other stakeholders to the purposes of regulation, the transparency was strengthened.

Once the Market Failure (Information Asymmetry) was detected, a regulatory response was required in order to make information clear and available to all the

stakeholders. Therefore, the Regulatory Impact Analysis helped to implement a compliance model with a view to providing higher quality health services.

4.4 The Qualification Process for Companies – A new Approach

The initial regulation of the private healthcare sector in Brazil focused on regulating the companies’ financial controls, the users’ rights and regulation of the products (private healthcare service contracts). Although this approach is important, the regulation specialists from ‘ANS’ recognized it was not enough to ensure consistent levels of care for users.

As a result, the regulators decided to change their approach: now the companies are considered to be healthcare managers and thus responsible for the outcomes and quality of care provided. This new trend also considers that constructing a comprehensive healthcare system should involve producing healthcare actions in the domains of health promotion, protection, convalescence and rehabilitation.54

Ribas55 argues that the core idea of the qualification programme (in accordance with the terms of the Management Contract signed by the Minister of Health and the ‘ANS’ President) is to emphasize that all actors playing a role in the market should aim to improve their performance. Profound transformations will arise from the following aims: the private health plans companies and medical insurers will become healthcare managers; the providers will become partners in the search for providing comprehensive services of a reasonable quality; the users will become more aware of their rights and the regulatory authority will often improve its regulatory strategies. This represents an attempt to adopt the responsive regulatory paradigm.

55 B Ribas ‘Processo Regulatório em Saúde Suplementar: Dinâmica e Aperfeiçoamento da Regulação para a Produção da Saúde’ (Law Department - Universidade Federal do Estado do Paraná; 2009)
The new challenge to be faced by ‘ANS’ now is to build new managerial and regulatory processes, with a view to forming a new model of providing healthcare services, that consider the user’s needs as a company’s first mission. Thus, evaluating and continuously monitoring the quality of care have become the preferred instruments for improving the companies’ performance.

The current trend for the ‘ANS’ regulators seems to be to set performance standards which require a given level of healthcare service provision at the action stage. In terms of performance standards (figure below), the quality of the healthcare plans companies is assessed through four dimensions\(^{56}\), namely:

I. Quality of Care (50%) – evaluating the actions of promotion, prevention and care taken by the firms;
II. Economic and Financial Quality (30%) – evaluating the solvency of a company, which means its ability to pay private providers;
III. Operational Quality (10%) – evaluating the quality of a company’s network (a firm shall own or maintain agreements with a wide range of healthcare services providers) which will be monitored by the regulators;
IV. Satisfying the beneficiaries (10%) – evaluating whether the users’ needs and expectations are being met by the companies.

4.5 Partial Conclusions

In order to conclude this chapter, the benefits to the users of health care services that were created after introducing economic regulation into the health sector shall be emphasised with a view to supporting the idea that using the best practices of the Brazilian Regulatory Model may be very useful for the British health care system.

In Brazil, the economic regulation in the health care system has been applied successfully for 12 years, since the creation of the Regulatory Agency ‘ANS’. The Brazilian Regulatory Authority carefully monitors the financial performance, as well as the quality of the health care services provided by the companies, through inspection regimes and intervention methods. This prudential regulation has proved to be very responsive to patients to the extent that their needs and expectations are being met by the health plan companies. Therefore, the regulatory tools and enforcement strategies discussed in this chapter might be applied by Monitor (the Economic Regulator for health care services in the UK).

Baldwin and Cave\textsuperscript{57} suggest that a regulatory evaluation system should take into account the arguments that have general currency when regulatory arrangements and performance are discussed in the public domain. These arguments involve receiving satisfactory results from one or more of five key tests:

1) Is the action supported by legislative authority?
2) Is there an appropriate scheme of accountability?
3) Are procedures fair, accessible and open?
4) Is the regulator acting with sufficient expertise?
5) Is the regime efficient?

It has been shown that the Brazilian Regulator is working hard to ensure the answers to these five questions are positive. As has been mentioned in this chapter, there is authorization from an elected legislature (Law 9656/1998). The regulators also have to achieve some targets outlined in the Management Contract, so they are accountable. Their administrative procedures – which are carried out by the Inspection Departments - are accessible and fair. Specialized knowledge skills do exist in ‘ANS’: the staff consists of experienced lawyers, economists, physicians, nurses etc. And the Qualification Process is being implemented efficiently.
5. CONCLUSION

Although comparing different regulatory regimes might seem to be a hard task for researchers, on the other hand, it is an opportunity for natural experiments, in which the relationships between different regulatory approaches, processes and interventions may be studied, as well as their impact, outcomes and effectiveness. This dissertation aimed to demonstrate that it is possible to maximize the healthcare regulation effectiveness in the UK and in Brazil by interweaving the best practices of the two systems.

In Chapter 3, it has been argued that the regulatory regimes should be designed to use the least intrusive and cheapest possible regulatory interventions to achieve their objectives. This is the parsimonious approach designed by Ayres and Braithwaite to minimise the costs of regulation to the regulator and to the regulated organisations; and to minimise the side-effects and unintended consequences of the regulatory methods and interventions. It is worth mentioning that this sort of regulatory regime has been a reality in Brazil for twelve years while it is very new to the British model of regulation.

It has been shown in Chapter 4 that the Brazilian inspection regimes and intervention methods have had very good outcomes so far. Therefore, these Brazilian regulatory tools might be interwoven with the British failure regime (also designed to deal with Foundation Trusts which fail to break even financially) set out by the Health and Social Care Act 2012. This prudential regulation could be used by Monitor with a strong focus on enforcing financial disclosure through financial reports, and the requirement of owning minimal capital and making actuarial provisions (these examples being drawn from the Brazilian Authority).

Furthermore, it is crucial to mention two Brazilian regulatory practices (outlined in section 4.2 above) that could be used by HealthWatch England:

a) **Administrative Measures** that operate without recourse to the courts and can be provided for in statutes or secondary legislation. For example:
fines, improvement and prohibition notices which require remedial actions to be taken within a fixed period or order the discontinuance of an irregular practice;

b) Commitment to Adjust Conduct which is a kind of agreement with the regulated organisation in order to prevent abuses against patients and to improve the quality of healthcare services (Compliance Regulatory Model).

It has been argued in Chapters 3 (Section 3.4.6) and 4 (Section 4.4) that regulation should be designed to support improvement across the spectrum of performance, not just to set minimum standards which become accepted norms. In other words, regulators should aim to empower organisations to do well, rather than impose requirements that may constrain or limit what they do.

Therefore, with a view to maximizing the effectiveness of healthcare regulation in the UK and in Brazil, the principles of responsive regulation outlined in Chapter 3 (contingency, hierarchy, flexibility, tripartism, parsimony and empowerment) should be used by both countries, especially by interweaving the best regulatory practices of the two systems. This seems to be the answer to the research question: ‘How could the new model of Economic Regulation for the Health Care Sector improve in order to protect patients’ interests?’

The key conclusion to draw from this study is that patients’ views must be taken into account and the best way to do this is through a well-designed system of regulation in health care, where there is a greater focus on outcomes, and where professionals and providers have the freedom to innovate and respond to patients’ needs and aspirations. The UK is going through a very special moment because a start is being made on designing the model of economic regulation in the health care sector. It is paramount that the decisions about this regulatory design are properly informed by theoretical and practical understanding of the processes of regulation. In this sense, the findings of this research have shown that the methods used by the Brazilian Regulator might be successfully applied by Monitor.
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