The King's Fund

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Economic regulation in health care

What can we learn from other regulators?

Key messages

- The coalition government has proposed giving extended powers to Monitor to act as a regulator for the health care sector. It will be responsible for price-setting, tackling anti-competitive behaviour, and ensuring continuity of essential services in the event of financial failure. The rationale is that, having established a market in health care, regulation is needed to ensure that the market operates in the interests of the public and patients.
- The original idea for a regulator in the health care sector was inspired by the experience of regulators in the former nationalised utilities. This paper seeks to take a dispassionate look at the potential lessons for the development of economic regulation in health care that can be learned from the experiences of both countries that have already implemented it and those of other market sectors in the United Kingdom. It will be essential reading for policy-makers considering the role of economic regulation in health care, and those tasked with implementing the new system of regulation in England.
- In all cases, the primary role of regulators is to protect consumer interests. Experience from other sectors suggests that if too many policy priorities are set, the regulator can become confused about its primary objectives, reducing its effectiveness. The government needs to reduce the number of objectives it has set Monitor and to give clearer guidance on how to trade off these differing objectives.
- The objectives of regulators have changed over time in response to changing circumstances, technologies and the market structure. The government should consider whether to put Monitor's objectives in secondary guidance, together with a clear process for how and when changes will be agreed with the Department of Health, in order to ensure flexibility but protect Monitor from political whim.

- The establishment of independent regulators was explicitly designed to take day-to-day decision-making away from the political arena. Monitor's independence could be further compromised if it has to resort to the government to resolve tensions with other regulators in health and related agencies. The government must provide greater clarity on how the Care Quality Commission (CQC), Monitor and the NHS Commissioning Board will work together to ensure their objectives are aligned.
- Monitor will continue to be accountable to parliament. In the case of other regulators, scrutiny by a parliamentary committee has been found to be unsatisfactory, partly because of a lack of objective measures against which performance can be judged. The annual report of Monitor needs to be sufficiently detailed to allow the performance of the regulator to be evaluated. There may also need to be a stronger role for the National Audit Office in assessing the performance of the regulator.
- HealthWatch England needs to act as a consumer champion and learn from the experience of Consumer Focus to ensure that Monitor and the CQC operate effectively in the interests of the public and patients. HealthWatch England needs to set out clear guidance for local HealthWatch groups to ensure that they understand 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.
- The experience of other countries suggests that the regulator should issue clear advice to providers to explain what will and what will not be tolerated in order to create a permissive environment in which integrated care can flourish. Monitor needs to send early signals about the approach it intends to take, particularly with regard to the arrangements for developing models of more integrated care.
- An essential role for Monitor will be to ensure continuity of access to essential services. 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. 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.
- 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 regulation will stifle innovation and integration. Monitor should adopt a facilitative approach, encouraging providers to take risks and innovate. It also needs to provide clear advice to providers wishing to partner, collaborate or integrate about the level of evidence required to demonstrate that such arrangements are in the public interest. It also needs to ensure that the tariff is set in such a way as to encourage the introduction of new, cost-effective treatments and models of care.
- The utilities' regulators have employed a wide range of regulatory tools and incentives. Not all of these will be applicable in the health sector, but many will be available to Monitor. This review suggests that they will need to be modified from the approach currently envisaged. The following need to be given early attention:
  - develop a pricing strategy that recognises the other (non-financial) incentives faced by providers, the feasibility of setting so many prices and the need for a transparent system of capital pricing
  - understand the interdependencies between services within current providers, and the implications of introducing transparency of accounting costs for monopoly services and competitive services

  - identify potential 'bottleneck' facilities and explore the implications for the relationship between those that own and manage facilities and the providers of clinical services
  - ensure Monitor has sufficient financial oversight of all providers to make judgements about their sustainability and risk of insolvency or financial failure
  - assess the feasibility of establishing an independent banking function for the NHS, and clear rules about how private investments will be handled in the case of failure.

- The task Monitor faces is also of a different order from that in any other sector. This is partly because of the diversity of the health care market, and partly because some of its features – such as the role of GPs and commissioners – are largely unparalleled elsewhere. Other regulators employ a significant number of sector-specialist economists (many of which they have trained). These are not available in significant numbers in either the NHS or the Department of Health. The regulator will also have a significant requirement for information in order to fulfil its functions. Monitor will need to work closely with the Information Centre to ensure that standardised data on the quality and costs of services are available for all types of providers, regardless of their ownership status.
- The expectation was that the creation of greater competition would diminish the need for intervention and regulation. This has not always been the case, indeed there is a risk that regulation adds to existing mechanisms for shaping the behaviour of providers, eg, commissioning and performance management.
- Economic regulation has been challenging to implement in other sectors. Monitor has been set a formidable task with little precedent and supporting analysis, so the risk of failure is considerable. Unless regulation is designed and executed well, it may impose more costs than it produces in benefits. It would be unwise to expect too much too quickly from the introduction of a sector regulator in health. It is likely that other drivers, such as commissioning and performance-monitoring, will play an important role for some time to come.

Introduction

The coalition government's White Paper *Equity and Excellence: Liberating the NHS* (Department of Health 2010) set out proposals to strengthen choice and competition in the NHS. The Health and Social Care Bill 2011 (House of Commons Bill 2010–11) detailed the legislative changes necessary to realise these reforms, including provisions to give new powers to Monitor. Currently the licensing authority for foundation trusts, a role it will continue to fulfil until 2016, under the new proposals Monitor will be given wide-ranging powers to impose licence conditions to prevent anti-competitive behaviour, to apply sanctions to enforce competition law, and to refer malfunctioning markets to the Competition Commission. Monitor as an economic regulator for the health sector as a whole, covering public and private sector providers, will also be responsible for setting prices (or tariffs) for NHS-funded services, and ensuring continuity of essential services in the event of financial failure.

The Bill draws heavily on the legislative framework used for regulators in other areas of the economy, such as telecommunications, utilities and railways. These economic regulators were originally set up to regulate natural monopolies in the interests of consumers and to promote competition where appropriate. Over time, as the market has developed, their role has evolved from being largely about economic regulation of market failures to encompassing more focus on the promotion of competition.

Interestingly, Secretary of State for Health Andrew Lansley's own ideas for the reform of the NHS, developed while in opposition, were born out of his experience of the privatisation and regulation of utilities in the mid-1980s when he was Principal Private Secretary to Norman Tebbit (who was Secretary of State for Trade and Industry during much of that time). In a speech to the NHS Confederation in 2005, when he was Shadow Secretary of State for Health, Lansley said: 'The combination of the introduction of competition with a strong independent regulator delivered immense consumer value and economic benefits.'

He went on to set out a number of guiding principles for the regulation of public services, including health care:

- maximise competition
- transfer risk to the private sector
- appoint a strong pro-competition regulator
- set out clearly the standards that must be met and how operators will be held accountable for them
- be clear about how and by whom universal service obligations are to be met
- ensure high-quality information for customers
- have more consumers rather than fewer (that is, don't have a few monopolistic health authority purchasers). (Lansley 2005)

He also argued for a 'strong and independent voice for the consumer standing alongside, but distinct from the regulator' (Lansley 2005). The aim of those original proposals appears to have been to promote competition throughout the health system. Many of these ideas are at the heart of the reform proposals being pursued now by the coalition government albeit with a greater recognition that competition needs to be applied only where appropriate.

The National Institute for Health and Clinical Excellence (NICE) has been tasked with setting out clear standards for commissioners to use to hold providers to account. Groups of GPs and other clinicians are being given budgets to buy services on behalf of

patients. Providers will be licensed by Monitor, and this process will make explicit which services they are obliged to provide – known as mandatory services in the foundation trust regime.

Under recent proposals for health special administration, commissioners will be able to apply to have conditions included in the licences of private providers to ensure continuity of essential services. HealthWatch has been established as the voice of patients, and Monitor will become a strong, independent regulator tasked with ensuring a competitive market in health care. These latter proposals attracted extensive opposition during debate of the Bill.

When David Bennett, Chair of Monitor and acting Chief Executive, used the example of utilities and rail regulation in an interview with *The Times*, he provoked much criticism and reaction from those who claimed that health care was nothing like water, electricity or railways. Critics of these proposals argue that competition in health care might be harmful rather than beneficial. Concerns tend to stem from a belief that competition will lead to a greater role for the private sector and the closure of publicly owned hospitals. There is also a risk that if competition results in more fragmentation in the delivery of health care, the potential benefits of integrated care will be lost (Curry and Ham 2010).

This paper seeks to take a dispassionate look at the potential lessons for the development of economic regulation in health care that can be learned from the experiences of both countries that have already implemented it and those of other market sectors in the United Kingdom. It will be essential reading for policy-makers considering the role of economic regulation in health care, and those tasked with implementing the new system of regulation in England.

We begin with a discussion of what is meant by economic regulation and why it is needed. We then briefly describe the development of economic regulation in England, set out the proposals for how economic regulation in health care in England will work, and describe the differences between health markets and those operating in the utilities.

The main part of the report looks at what can be learned from the experience of other sector-specific economic regulators in the United Kingdom. In particular, we consider what objectives they have, how they are held to account, and what regulatory instruments they use to fulfil their functions.

We then briefly compare the coalition government's proposals for England with the experience of economic regulation in health care in The Netherlands and the United States, and conclude with a discussion about the implications for the establishment of Monitor and which issues need to be considered if the new approach to regulation in health care is to deliver benefits.

Definitions and development of economic regulation

What is economic regulation?

The need for economic regulation arises from the risk that markets will not be competitive, eg, where there are monopoly suppliers with the potential to restrict output (quantity, quality, or both) and charge high prices for their products, unconstrained by the threat of other firms entering the market; or where potentially competitive suppliers attempt to restrict competition through mergers or indulge in forms of anti-competitive behaviour such as price fixing that may be harmful to users.

Another reason for regulation is the existence of externalities. For example, a hospital might devote resources to training staff who subsequently 'defect' to another institution, thus reducing the incentive to provide such training and potentially leading to a shortfall

in skilled staff. Regulation may be required to ensure that the actions of independent bodies – foundation trusts or privately owned providers – do not conflict with what is desirable for the system as a whole.

Some supporters of free markets argue that regulation can be more damaging than the market failure it is designed to address. Proponents of independent economic regulation believe that an effectively functioning market can deliver improvements in quality and efficiency. Others are more critical and highlight the risks of regulatory failure, which include:

- providers having undue influence over the regulator (capture)
- the original purposes being overlaid with other objectives (goal displacement)
- the scope and scale of regulation extending to the point where it is disproportionate (proliferation)
- regulation inhibiting change and innovation (ossification)
- regulators becoming self-serving (unaccountability)
- regulation becoming legalistic (legalism). (Walshe 2003)

There have also been attempts to set out what the principles of effective regulation are, and within government the Better Regulation Executive has been working to reduce the burden of regulation (Department for Business, Innovation and Skills 2011a).

The development of sector-specific regulations can be traced back to the 19th century, when various Acts of Parliament were introduced to ensure that railways served the public interest rather than exploiting their monopoly power (Foster 1992). Successive Acts required the private rail companies to obtain permission if they wanted to raise charges, and also required some fares to be set at levels that working people could afford.

In the 20th century, particularly after the Second World War, public ownership was the main method for ensuring that industries such as electricity, gas, telecommunications, transport and water could not exploit their monopoly powers. For more than 50 years, local or regional utility monopolies were actively promoted by government in the belief that the existence of economies of scale meant that these were the most efficient (ie, lowest cost) forms of provision.

Until the 1980s, government policy had aimed to make publicly owned utilities operate more efficiently through, for example, the introduction of demanding financial targets (Her Majesty's Treasury 1978) and tight control of capital spending. These financial targets effectively determined the overall price levels of the utilities, and thus limited the extent to which the utility companies could exploit consumers through high prices.

However, it became apparent that although in principle a monopoly might seem to be the most efficient form of provision because it allowed economies of scale to be fully exploited, in practice performance was often poor in terms of both cost and quality. The Conservative government elected in 1979 decided that this form of exploitation could be addressed through privatising the industries and making them subject, wherever possible, to competition.

It was recognised that privatisation would not in itself create competition. In the case of British Telecom (the first major privatisation) the government paved the way for one new entrant, Mercury, by deferring the entry of other providers for seven years. That still left British Telecom with substantial market power. The government came up with what was then a novel solution – the appointment of an independent regulator, initially a named individual, to actively promote competition and protect consumers' interests in respect

of prices and service quality, and also to reassure potential investors in the privatised company that it would not be subject to arbitrary government interference.

Independent regulation has now become the standard approach in the United Kingdom and many other parts of the world, particularly for power, water and telecommunications. Appendix 1 (*see* p 40) gives a brief introduction to four of the key economic regulators in the United Kingdom.

In otherwise competitive markets that are not subject to sector-specific economic regulation (of the type described above), the national competition authorities ensure that the market operates fairly in the interests of consumers. The responsibility currently sits with two non-departmental public bodies – the Office of Fair Trading (OFT) and the Competition Commission, although it has been proposed to merge them (Department for Business, Innovation and Skills 2011a).

The Competition Act 1998 created powers for the OFT to investigate practices that might restrict competition and choice and provided for the imposition of penalties. The OFT's purpose is to 'make markets work better for consumers, ensuring vigorous competition between fair dealing business and prohibiting unfair practices such as rogue trading, scams and cartels'. Its market investigations may lead to enforcement action, consumer awareness campaigns, recommendations for government, or referral to the Competition Commission.

The Enterprise Act 2002 provided for referral to the Competition Commission if a market has features that might prevent, restrict or distort competition. The Competition Commission conducts in-depth inquiries into mergers, markets and the regulation of the major regulated industries in response to a referral from another authority, usually the OFT but also from sector-specific regulators, most of which were given concurrent powers with the OFT by the Competition Act 1998. The Competition Commission enjoys wide-ranging powers to remedy any competitive concerns it identifies, including prevention of mergers or forced sale of parts of a business. In respect of the regulated industries, it considers cases where a company does not agree with a modification to its licence proposed by the regulator. When enforcing its decisions it does not require approval from government.

So, in regulated sectors of the economy, three main functions co-exist, and are applied differently, depending on the structure of the market, to:

- tackle abuse of a dominant position by a monopoly provider
- promote competition where appropriate
- ensure competition is working effectively by tackling anti-competitive behaviour.

It is only in the third domain that the regulator acts as a competition authority.

In this paper, we use the term economic regulation to comprise all of the measures designed to deal with market failures, ie, both sector-specific measures and the wider framework of competition law. Before looking at what we can learn from these other regulators, we give a brief overview of the development of economic regulation in the NHS.

The development of economic regulation in the NHS

During the 1990s, the Conservative government created an internal market in the NHS, with the separation of purchasers (health authorities and GP fundholding) and providers (public providers were given greater autonomy as trusts). These reforms largely failed to

live up to the claims of their proponents or the fears of their critics, principally because the incentives of the internal market were too weak and the constraints imposed too strong (Le Grand *et al* 1998).

Having initially rejected a market in health care when first elected in 1997, in the years following the NHS Plan (Department of Health 2000) the Labour government gradually returned to market-based approaches in the belief that centrally directed policies were not sufficient to drive the improvements in performance it was seeking to achieve. These market reforms went far closer to introducing market competition into the NHS than the Conservatives' internal market in the 1990s (Mays *et al* 2011).

The King's Fund argued 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' (Lewis *et al* 2006, p 57).

Independent regulation was established during this period, but the focus was on ensuring that all providers met minimum quality and safety standards (CQC), and that the governance of foundation trusts was sufficiently robust to allow them to have greater operational autonomy (Monitor), rather than 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 covered mergers, anti-competitive conduct, misleading advertising and the procurement of NHS services.

The Co-operation and Competition Panel was established to advise on whether cases referred to it were infringing the rules, as well as on the acceptability of proposed mergers. The Co-operation and Competition Panel's role is advisory only, however, and the Department of Health remains the final decision-maker in relation to mergers or other threats to competition.

Experience with the application of these rules has so far been limited. Most of the proposed mergers were judged unlikely to reduce competition to a significant degree. However, in 2010 private sector providers complained that they were not being allowed fair access to contracts. The Co-operation and Competition Panel examined the complaints, and in its final report, published in July 2011, confirmed that some primary care trusts were acting in a manner inconsistent with the principles and rules – limiting patient choice and restricting the ability of providers to offer routine elective services (Co-operation and Competition Panel 2011).

Thus far, neither the OFT nor the Competition Commission has had an explicit role in relation to the NHS, although some of the OFT's investigations into privately provided services (where its remit is clearer) have had implications for the NHS. In the case of community pharmacies, for example, the OFT concluded that the entry control operated by the local NHS itself, which required demonstration of the need for an additional provider of community pharmacy services in a specific area, should be abolished (Office of Fair Trading 2003). This recommendation was not accepted in full by the government at the time, although a number of exemptions from entry control were introduced, eg, for supermarkets and for pharmacies opening for at least 100 hours per week. The OFT is currently reviewing the role of the private sector and NHS providers in treating private patients (Office of Fair Trading 2010).

EU competition law applies only to 'undertakings', but there is no legal clarity about whether this term applies to NHS trusts and foundation trusts. Although there has not

been a test case, foundation trusts are likely to be considered 'undertakings', particularly as they are allowed to compete for private patients. The lifting of the private patient cap, which sets a limit on the proportion of trust income that can be raised from private patients, will make this more likely.

So far, public organisations (including primary care trusts) that have a purely social function have been considered exempt from competition law. However, commissioners are subject to Department of Health procurement guidance and EU procurement principles, which comprise equal treatment, transparency, proportionality and mutual recognition. Under the EU principles, there is no requirement to tender. A commissioner is free to decide to provide services itself but if it decides to tender, then it must comply with the principles ensuring a fair and transparent tendering process.

The *Rules and Principles of Co-operation and Competition* (Department of Health 2008b) and *Primary Care Trust Procurement Guide for Health Services* (Department of Health 2008a) were intended to ensure that the NHS was operating within the parameters of competition law so that the NHS would not be found wanting if a challenge were brought. So, although these principles and the advice of the Co-operation and Competition Panel have not had legal backing, the NHS has already been subject *de facto* to many of the requirements and provisions of competition law.

The coalition government proposes to give more explicit powers to the competition authorities and to establish Monitor as an independent economic regulator. We examine the plans below.

What is the coalition government proposing?

The proposals set out in the coalition government's White Paper *Equity and Excellence: Liberating the NHS* (Department of Health 2010) and subsequently in the Health and Social Care Bill 2011 (House of Commons Bill 2010–11) can be seen as a continuation of the market-oriented policies of the previous Labour government. However, they go further by creating a stronger and more independent system of economic regulation that will apply to the whole health care sector, including both public and private providers, and may be extended to social care (of which more later). It is clear that EU competition law, which covers state aid, mergers, cartels and the prevention of monopolies, will apply now that the NHS has been brought within the scope of the Competition Act 1998 and the Enterprise Act 2002.

The Health and Social Care Bill proposes to increase and extend Monitor's responsibilities substantially, to include:

- price-setting
- tackling anti-competitive behaviour
- ensuring continuity of essential services (in the event of financial failure).

It will continue to be responsible for the authorisation of foundation trusts until 2014 (the deadline by when all trusts need to have been authorised as foundation trusts). In addition, because of concerns about changes in the governance of foundation trusts, Monitor will maintain its oversight of foundation trusts until 2016.

Monitor will acquire, from the Department of Health, the responsibility for setting the national tariffs that will be used to reimburse the NHS and other providers for their services. Responsibility for the overall design and structure of the tariffs, however, will fall to the NHS Commissioning Board. Currently, the tariff applies to only some hospital services, but the intention is to extend it to the majority of both hospital and community

services. The government has made it clear that it does not want price competition: because prices will be fixed, providers will be expected to compete on the basis of quality. Additional payments above the tariff might be agreed if there are legitimate reasons why, even when operating efficiently, a trust is unable to maintain safe services, such as in a rural location.

The Bill provides for Monitor to have concurrent powers with the OFT under the Competition Act 1998 and the Enterprise Act 2002, meaning that Monitor will have the power to examine complaints about anti-competitive behaviour or abuse of the market and to seek a remedy.

In response to concerns that the original Bill placed too much emphasis on promoting competition, the government tabled a number of amendments, of which the most important was a change to the duties of the economic regulator. Monitor's main duty will be to protect and promote the interests of those using health services 'by promoting provision of health care services which is economic, efficient and effective, and maintains or improves the quality of services' (House of Commons Bill 2010–11, as amended 8 September 2011, p 87). It will be required to exercise its functions with a view to preventing anti-competitive behaviour that is not in the interests of patients rather than positively encouraging competition. In addition, the government responded to the criticism that more competition would lead to greater fragmentation of services by requiring Monitor to support the delivery of integrated services where this would improve quality of care for patients or reduce inequalities in access and outcomes.

In a competitive market, if providers are not able to respond to loss of business by improving or changing their services to attract consumers, they may ultimately go out of business. Historically, in the public sector, providers have not been allowed to fail. The Bill has introduced clearer arrangements for dealing with providers that are 'financially unsustainable'. Monitor will have the power to intervene when a foundation trust is 'in distress', for example by appointing a turnaround team. Only if a foundation trust is unable to turn itself around and becomes financially unsustainable will a process of administration be put in place to secure continuity of access to those services. The government also proposes that private providers of essential services will be subject to a similar regime, albeit within a different legal framework (Department of Health 2011b).

Market structures

Before drawing lessons from the regulators in other sectors, it is important to understand how the market in health care differs from those for other goods and services.

In some areas there are close similarities: like the utilities, hospital services are highly concentrated; and in some local health markets there is only one hospital provider, which could be judged to be a dominant supplier using the tests applied by competition authorities in other sectors.

The dominant position results from a belief that larger units are more efficient than smaller ones. 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. In some parts of the country, such as London and other conurbations, hospital catchment areas overlap and users have an effective choice of more than one hospital (Beckert *et al* 2011); but in many areas, only one hospital providing the full range of hospital services is within easy reach of the local population. In these areas, the position of hospital trusts is similar to that of the utilities before the break up of monopolies. As with the utilities, there is a risk of 'exploitation' through failure to improve performance in terms of quality and cost.

In addition, for some services – such as those for patients with cancer or stroke or who need emergency care – hospitals typically, though not universally, work as part of a clinical network covering a substantial area of the country, collectively enjoying a monopoly position. There is no direct parallel between these networks and those of the utilities. Clinical networks are 'virtual', ie, they consist of agreements or protocols about where and how patients should be treated. Utility networks, in contrast, are physical 'pipes and wires'. Nevertheless this raises the issue faced by utility regulators of whether further consolidation into fewer suppliers should be allowed on the grounds of increased efficiency or better quality, if, at the same time, it threatens to reduce competitive pressures.

In addition, a number of highly specialised services are provided by only a small number of hospitals. These are commissioned nationally or regionally, and will continue to be in future by the NHS Commissioning Board. For these services, competition on a day-to-day basis is impractical, although competition *for* the market on an occasional basis might be feasible through franchising, a model adopted for the rail industry.

However, not all hospital services share these characteristics. In the case of elective and diagnostic services, a market has already been established, allowing patients to choose between different providers. One issue here is whether patients have access to the information they require in a suitable form to do so effectively, something that has arisen in the power industries, as we see below.

For non-hospital services, economies of scale and scope are less important, so prima facie competition is also feasible. However, as the work of the Co-operation and Competition Panel has shown, it might not develop, even where the underlying economics support it, if the framework created by the Principles and Rules for Cooperation and Competition is not adhered to.

Thus the health care sector, like the utilities sector, comprises a mix of monopolised markets at national, regional and local level, and actual or potentially competitive markets primarily at local level.

However, the health sector is different in some key respects. None of the utilities contains as many providers, and none provides such a vast range of different services. Health care is funded out of general taxation rather than charges to consumers, and the greater part of provision remains in the public sector. The capital market disciplines that apply to the utilities sector are therefore much weaker.

There is no parallel in the health care sector to the commercial markets that exist in the power industries, in particular. There is also no close parallel in the utilities to the complex role of GPs as advisers, providers and, in future, commissioners. Quality is, in general, much harder to assess, and cannot be measured by technical standards such as those that can be applied to the electricity or gas markets, making it harder than in those industries for regulators to monitor the quality of care and for users to make informed choices.

Finally, the tension between competitive and integrated services is more acute in the health sector. In the rail, power and telecoms industries, different organisations must co-operate if the various elements required to deliver a service are to work effectively. One of the roles of these industries' regulators is to ensure that such co-operation is possible while competition is maintained, eg, through imposition of common technical standards. In the health sector, however, the measures required to ensure integration between the services of different providers will generally require ways of working that limit or even curtail competition, at least on a day-to-day basis.

Because of these differences, any comparison between health and the utilities must be made carefully. Nevertheless, the new health regulator will face a number of issues that do closely parallel the experience of the utility regulators. We draw selectively on their experience, as well as on the *Principles for Economic Regulation* (Department for Business, Innovation and Skills 2011c), which sets out in broad terms the government's policies towards economic regulation. Although not addressed to the health sector, it deals with many of the issues involved in the establishment of an independent regulator for health services.

What can be learned from the experience of other sector regulators?

In this part of the paper we draw selectively on the experience of the regulators in the telecommunications, power, rail, postal and water industries to explore some of the issues that Monitor will face.

There is general agreement that the independent regulatory regime has been successful. The House of Lords Select Committee on Regulators (2007), for example, found that '…on the whole, the legislation is thought to be working well and the regulators and regulated industries are satisfied with its provisions' (p 9).

The regulators are seen as being genuinely independent, ie, not subject to day-to-day intervention, albeit within a framework set by government, which might constrain or determine how they operate. There also seems to be agreement that the framework *should* be set by government, leaving the regulator to work out the mechanics.

In some industries, particularly telecommunications and energy (including gas), independent regulation is seen as having been successful in reducing prices (although some of these gains are no longer apparent as energy prices have been rising in recent years), encouraging innovation, and giving consumers greater choice (National Audit Office 2002). In others, such as water and rail, there has been less success in these areas. For example, in the case of rail, the House of Commons Committee of Public Accounts (2011b) has been very critical of the performance of the rail regulator in respect of Network Rail's high costs; and in the water industry, competition and user choice remain very limited.

However, these shortfalls have not led to a demand for an end to independent regulation, but rather for the regulator to be more effective in the industries concerned, suggesting a strong belief that the costs of market failure are greater than the costs of regulatory failure.

Support also comes from the capital markets, because independence provides investors with greater stability, making it easier to fund sufficient levels of capital investment, as the government itself has noted (Department for Business, Innovation and Skills 2011b). In addition, the independent regulator model might offer benefits in terms of freedom from political interference, greater scope for focusing on long-term issues, concentration of industry-specific expertise, more transparent decision-making and better evidenced decisions (Consumer Focus 2010).

Initially the regulatory role turned on curbing monopoly power, creating the scope for competition and then setting and enforcing the rules by which market participants should abide. The expectation was that these would deliver the desired results – lower prices, greater efficiency and better-quality service – and that, as competition was introduced, the need for regulation would, at least partly, disappear. In the case of telecommunications and power these expectations have mostly been realised for a large part of the market; but in the power industry regulation is now seen as a means of promoting objectives such as national security of supply, which the market by itself would be unlikely to achieve.

It has been argued that the creation of markets has led to an increase in regulation (Majone 1994). There is also a risk that increasing the role of regulation in health care adds to existing mechanisms for shaping the behaviour of providers, such as commissioning and performance management.

What objectives do the regulators have?

The objectives for the regulators set out in legislation have been modified over the years, and there remain differences between them (*see* Table 1 below). These differences reflect the varying characteristics of the industries they regulate: for example, only Ofgem has a duty to maintain security of supply. However, protecting consumers' interests forms part of the role in all cases, and all the utility regulators have a duty to promote competition and protect vulnerable groups.

The objectives set out in the table do not, however, capture the full extent of the regulatory role. In the case of the power industries, for example, additional objectives have been introduced as government policy has changed. In 2002, the government published social and environmental guidance for the gas and electricity markets' authority, which has since been updated. The latest guidance stated that Ofgem has an important role in encouraging the development of the national energy system including:

- enabling timely delivery of an effective offshore transmission regime
- enabling timely investment in necessary capacity
- ensuring connection to the electricity network for new generation suppliers
- eliminating unnecessary barriers to the economic deployment of distributed energy
- making further progress to eliminating fuel poverty
- ensuring network resilience. (Department of Energy and Climate Change 2010, pp 5–6)

Table 1 Summary of the statutory duties of economic regulators

Statutory duties	Ofcom	Ofwat	ORR	Ofgem	CAA	Postcomm	FSA	TPR	OFT
Further/protect the interests of consumers	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Further/protect the interests of citizens	Yes	No	No	No	No	No	No	No	No
Protect specified vulnerable groups	Yes	Yes	Yes	Yes	No	Yes	No	No	No
Promote competition	Yes	Yes	Yes	Yes	No	Yes	No	No	Yes
Facilitate market innovation	Yes	No	No	No	No	No	Yes	No	No
Encourage market investment	Yes	Yes	Yes	No	Yes	No	No	No	No
Maintain security of supply	No	No	No	Yes	No	No	No	No	No
Maintain the competitive position of the United Kingdom	No	No	No	No	No	No	Yes	No	No
Implement the five principles of good regulatory practice	Yes	No	No	Yes	No	No	No	No	No
Facilitate the development of self-regulation	Yes	No	No	No	No	No	No	No	No
Promote public awareness	Yes	No	No	No	No	No	Yes	Yes	Yes
Carry out impact assessments	Yes	No	No	Yes	No	No	Yes	No	No
Provide advice to the government	No	No	No	No	Yes	Yes	No	No	Yes

Notes: ORR, Office of Rail Regulation; CAA, Civil Aviation Authority; FSA, Financial Services Authority; TPR, The Pensions Regulator; OFT, Office of Fair Trading

Source: House of Lords Select Committee on Regulators (2007)

This extension of the objectives that regulators are required to promote represents a shift in the nature of the regulatory role. The introduction of new objectives and considerations has led to questions about the respective roles of the regulator and the central department. In evidence given to the recent Ofgem review, for example, a number of responses argued for greater clarity of roles between regulator and government. The National Grid (2010) argued, for example: 'The structural model of independent regulation… has one glaring weakness – the potential difficulty of co-ordinating policy and implementation between government/department and the independent regulator.'

Similarly Consumer Focus (2010) has argued for 'clarity about how government and regulators plan to work together, and government should set the strategic framework in which they want the regulators in each sector to operate' (p 4). This requirement has been endorsed by a recent paper from the Department for Business, Innovation and Skills (2011b), which stated (p 4): 'Independent regulation needs to take place within a framework of duties and policies set by a democratically accountable Parliament and government'.

Following a review of Ofgem begun in 2010, the Department of Energy and Climate Change committed itself to providing a strategy and policy framework to be underpinned by primary legislation. This will include:

- a clear description of the government's strategic roles for the gas and electricity market
- a description of the roles of government, regulator, business and other organisations in the energy market
- a clearly defined set of policy outcomes that Ofgem will have to deliver and against which it will be required to justify its regulatory decisions. (Department of Energy and Climate Change 2011)

The statement will be subject to parliamentary approval and, unless there is a significant change in policy, will last for at least the length of a parliament. Nevertheless, the review report makes it clear that Ofgem will still have to consider trade-offs between economic and broader goals (Department of Energy and Climate Change 2011, para 89, p 27), although it will fall to the Department of Energy and Climate Change to do so at strategic level.

Monitor's objectives as set out in the amended Bill require it to take account of a number of considerations over and above its primary duties in relation to competition and integration (*see* box opposite).

It seems likely that Monitor will find itself in the position of Ofgem and, to a lesser extent, that of other regulators of having to devise policies, particularly in relation to the tariff, to meet a wide range of objectives over and above its primary duties. The experience of Ofgem in particular suggests that this risk might grow over time as governments seek solutions for new problems as and when they arise. Setting too many policy priorities could carry the risk of confusing the regulator about its primary objectives, reducing its effectiveness. This might be inevitable given the complexity of health care policy-making, but it means that the accountability of the regulator is of critical importance. Nevertheless, the government might need to consider reducing the number of objectives.

For the other regulators, the government has committed itself to updating the objectives only once per parliament and ensuring that the objectives are outcome-focused. Monitor's objectives are currently set in primary legislation. The government should consider whether to put the objectives in secondary guidance, together with a clear process for agreeing to changes in the objectives with the Department of Health in order to protect the regulator from political whim.

Monitor's objectives

When carrying out its duties, Monitor must take account of:

- the need to maintain the safety of people who use health care services
- the desirability of securing continuous improvement in the quality of health care services for the purposes of the NHS
- the desirability of securing continuous improvement in the efficiency with which health care services are provided for the purposes of the NHS
- the need for commissioners of health care services for the purposes of the NHS to ensure that the provision of access to the services for those purposes operates fairly
- the need for commissioners of health care services for the purposes of the NHS to ensure that people who require health care services for those purposes are provided with access to them
- the need for commissioners of health care services for the purposes of the NHS to make the best use of resources when doing so
- the desirability of persons who provide health care services for the purposes of the NHS co-operating with each other in order to improve the quality of health care services provided for those purposes
- the desirability of promoting investment by persons who provide health care services for the purposes of the NHS in the provision of health care services for those purposes
- the need to promote research into matters relevant to the NHS by persons who provide health care services for the purposes of the NHS
- the need for high standards in the education and training of health care professionals who provide health care services for the purposes of the NHS.

Source: House of Commons Bill (2010–11) as amended 8 September 2011, pp 89–90

The Bill provides for the Secretary of State to issue what is termed a mandate, ie, a statement of what the government expects the NHS to achieve over a period of several years, but currently this applies only to the NHS Commissioning Board and can be updated annually. The government has also consulted on an NHS Outcomes Framework, which will be used at a high level to hold the NHS to account. There is a risk that Monitor's objectives will not be aligned with those set for the NHS Commissioning Board, causing tensions between the two bodies. There is also a risk of confusion for providers, who may face conflicting demands from the NHS Commissioning Board, local commissioners and Monitor, and regulatory overload arising from the need to satisfy different requirements for data.

Trade-offs between objectives

Even when the main duties of the regulators have remained focused on competition and consumer protection, the need for trade-offs between objectives has arisen. However, the legislation that defines the roles of the regulators provides little guidance on how such trade-offs should be managed. Regulators have adopted a variety of strategies to handle the problem.

One common trade-off is between cost and quality. In the case of water, the regulator Ofwat calculated what it would cost to raise water quality to specific levels, and put the issue to the minister for a decision. This approach was feasible for water because of the simplicity of its product, and could be justified by the fact that an increase in water charges would, in effect, be a tax, and so should be a matter for government rather than the regulator.

Another approach has been to use consumer research and surveys to derive a 'willingness to pay' measure to gauge support (or otherwise) for higher-quality standards. Ofgem recently commissioned the RAND Corporation to estimate the value users place on specific aspects of quality, such as reduced frequency of interruptions to supply and the level of compensation offered when interruptions do occur. Information of this kind, if reliable, could be used to support the introduction of incentive tariffs (*see* below) to incentivise companies to meet specific service standards. Regulators have acknowledged the need for such incentives because putting pressure on prices to prevent the regulated companies from making excessive profits carries the risk of a reduction in the quality of service as the companies seek to maintain profitability.

Measures of this kind might be useful for determining trade-offs such as those between cost and quality or access, but as the objectives facing the regulators have widened to include broader public policy concerns, the trade-offs have become more complicated and are more likely to involve political issues. The *Principles for Economic Regulation* (Department for Business, Innovation and Skills 2011b) argues for a clear separation between, on the one hand, those matters that require democratic accountability and should therefore be made by government, and, on the other, detailed application, which can be left to regulators. However, it also acknowledges that the dividing line might be hard to draw so that, although a clear delineation of the respective duties of government and regulator is desirable, it may not be fully achievable. Even if it is, however, the wider the number of objectives the regulator is set, the greater is the risk of conflict between them. The *Principles for Economic Regulation* does not directly address how these should be handled.

The quality/cost trade-off is of course a central issue for the NHS. As things currently stand, this trade-off lies at the intersection between NICE's standard setting, CQC's quality assessment, and Monitor's price-setting. At present, it is unclear how such cross-regulator issues will be resolved. Because of the range of services provided in the health care sector, it would be quite impractical to follow the Ofwat route of consulting ministers on each and every trade-off. However, the Ofgem approach has been used within the health care sector to determine the relative importance to patients of the various hospital attributes that influence their choice of place of treatment. It is not yet part of routine analysis in, for example, Department of Health impact assessments, however.

As for the potential conflict between broad objectives, the Bill requires Monitor to be explicit about how its decisions are made in the following terms.

- *If Monitor secures the resolution of a conflict between its general duties in a case that comes within subsection (5), or that Monitor considers is otherwise of unusual importance, it must publish a statement setting out:*
  - *the nature of the conflict*
  - *the manner in which it decided to resolve it*
  - *its reasons for deciding to resolve it in that manner.*

(House of Commons Bill (2010–11), para 63 (4))

Although this may provide material for public debate, it still appears to leave a large amount of discretion with the regulator as to how the balance between objectives should

be struck. The government may need to consider giving clearer guidance to Monitor on the relative importance of these objectives in order to enable them to make appropriate trade-offs.

How are they held accountable?

The establishment of independent regulators was explicitly designed to take day-to-day decision-making away from the political arena, partly to reduce regulatory risk to investors. The legislation provides for the regulators to be accountable to parliament through the relevant House of Commons select committee (as well as the Public Accounts Committee), and to be free on a day-to-day basis from political interference. This line of accountability has resulted in a number of parliamentary reports that have revealed both successes and shortcomings in performance. However, the legislation does not provide for externally set performance measures against which the regulators' performance can be measured (National Audit Office 2010).

The House of Lords Select Committee on Regulators (2007) found these arrangements unsatisfactory, concluding that 'there is a crucial need for greater parliamentary oversight over regulatory bodies' (p 7). It also recommended that 'an effective and transparent mechanism needs to be put in place for resolving potential policy conflicts so that the regulators are able to carry out their economic function without interference' (p 13).

Monitor is currently accountable to parliament under the provisions of the Health and Social Care (Community Health and Standards) Act 1983. The current Bill requires Monitor to prepare an annual report that must 'in particular, set out the measures that Monitor has taken to promote economy, efficiency and effectiveness in the use of resources for the exercise of its functions' (House of Commons Bill 2010–11, as amended 8 September 2011, p 367). This must be laid before parliament and a copy sent to the Secretary of State. Monitor will be required to respond in writing to any recommendations made by a committee of the House of Commons. In addition, the amendments to the Bill make it clear that the Secretary of State will hold Monitor to account (along with other NHS bodies) and report on its performance in his or her annual report on the health service.

Extreme cases apart, the Secretary of State will not have powers of intervention, however. So, even if Monitor were judged to be performing badly in terms of, for example, its judgements on specific competition infringements, the Secretary of State would not be able to seek specific changes to Monitor's methods of assessment. However, in such a highly politicised area of public policy as health care, it remains to be seen whether this lack of governmental oversight will prove acceptable, particularly where contentious issues such as hospital closures are involved.

In a separate development, the Health Committee has instituted a programme of annual accountability reviews for health sector regulators that so far includes Monitor, the CQC, the General Medical Council and the Nursing and Midwifery Council. This could be an effective mechanism for raising issues about Monitor's performance, particularly if the National Audit Office supports the Health Committee by offering briefing material, as it has done for the Energy and Climate Change Committee in relation to Ofgem (National Audit Office 2010).

In some cases, the regulators have made up for a lack of formal accountability by conducting their business in an open way, through informal and formal consultation with stakeholders on the basis of detailed technical work, and publication of documents supporting the decisions they make. For example, the latest Ofgem consultation involved a large number of separate elements, including several discussion papers and a large

number of technical papers, all of which were available for comment. The *Principles for Economic Regulation* endorses this approach, stating: 'Effective accountability of a regulatory framework… depends on transparency, a requirement to explain decision making, exposure to scrutiny and the right to challenge decisions' (Department for Business, Innovation and Skills 2011b, p 9).

Another approach has been to 'listen to users' and address the concerns identified. For example, the Communications Act explicitly requires that Ofcom conducts market research into users' preferences and sets up a consumer panel.

Consumer Focus – a national consumer organisation – has published a series of reviews of individual regulators, which revealed that a variety of processes had been adopted in order to ensure that the consumer voice was heard. Consumer Focus concluded that there were still gaps to be filled, however. For example, although broadly favourable, its report on Ofcom argued that that regulator had relied too much on self-regulation by the industry with the result that some of the problems users faced were not addressed (Brooker and Taylor 2009 pp 90–93).

A number of new initiatives to engage users is also under way. For example Ofwat (2010) has developed a service incentive mechanism that is designed to encourage companies to respond to consumer concerns. It is based on the number of complaints and the extent to which users were satisfied with how their complaints were dealt with. The results can then be used to modify each company's price limit, albeit within a narrow range of +0.5 per cent to –1 per cent. Similarly, Ofgem (2010a) has published proposals for what it terms enhanced engagement designed to allow all those affected by the current regulatory settlement to engage with it through a price control review forum, along with a number of other methods such as large-scale surveys among domestic users.

The government's response to the NHS Futures Forum indicates that it intends to place a duty on Monitor to carry out patient and public involvement in the exercise of its functions, and will be required to respond in writing to advice from HealthWatch England. HealthWatch at the national level is to be established as a committee within the CQC. Its role is to support local HealthWatch organisations and also to advise Monitor, the NHS Commissioning Board, local authorities and the Secretary of State on the views of health and social service users and the general public on their needs, their experience of services, the standards of care available in local HealthWatch areas, and the need for improvement where appropriate.

HealthWatch England needs to be clearly seen as a consumer champion and to learn from the experience of Consumer Focus in effectively ensuring that Monitor and the CQC operate in the interests of the public and patients. It 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 could require escalation to the regulator. There is a real danger that HealthWatch will be seen to replace existing forms of public involvement in local decision-making, which is not primarily its purpose or function.

What instruments do they use?

Economic regulators have a range of regulatory instruments at their disposal to shape the market, ensure fair competition, and maintain continuity of essential services. The key ones used in other sectors include price control, ensuring access to capital, promoting entry to the market including by opening access to facilities, promoting consumer choice, and ensuring continuity of services.

Price control

One of the key abuses of a dominant or monopoly position is the ability to set prices that are higher than they would be in a competitive market. All the industries brought under economic regulation possessed considerable monopoly power at the time of their privatisation, so some form of price control was required. The form adopted across most of the regulated industries is known as RPI–*x*, ie, changes in prices were allowed in line with the retail price index (RPI) minus some factor *x* to be determined by the regulator of each industry. The formula is set for a period of years ahead, giving the industries a strong incentive to overperform, ie, reduce costs by more than *x* per cent per annum provided they are confident that there will be no claw-back in the event of their making larger than anticipated profits.

Calculating how large *x* should be required taking a view on the scope for greater efficiencies in the industries concerned. The view at the time of privatisation was that the nationalised industries had been inefficient and that there was therefore scope for substantial price reductions. Nevertheless, the choice of what *x* should be remained, to some degree, arbitrary since there was no firm evidence about the scale of inefficiency.

In a speech in 2005, the then Shadow Secretary of State for Health, Andrew Lansley, recalled some of Norman Tebbit's early negotiations with British Telecom: '[British Telecom] said that anything more than RPI minus one – would be unacceptable. Norman said he'd go to RPI minus three and they'd have to live with it. He did and they did. Subsequently, they lived with regulatory price determinations as dramatic as RPI minus 12' (Lansley 2005).

The RPI–*x* regime still remains in place in markets such as electricity transmission and water where competition has not developed, but it has been modified in the light of experience. In the case of water, for example, it came to be recognised that *x* had to be positive (or a positive factor *k* added to the formula) to enable the industry to raise finance for improvements in water quality. This requirement is discussed further below.

How *x* should be set remains problematic. It remains hard for the regulator to judge what *x* should be and, as a result, the price control process has started to revert to a form of rate-of-return regulation. In this modified form, allowances are made for future running and capital costs, as well as for the potential to reduce both through greater efficiency. This still requires a judgement to be made on *x*, but, in theory, it is made on the basis of a larger amount of information than was used in the early days of price regulation.

The latest consultation papers for the power and water industries reflect the current view that RPI–*x*, already modified in practice, needs to be modified further to accommodate objectives other than competition and price control. Ofgem proposals for the electricity industry have developed a new approach known as RIIO (**R**evenue = **I**ncentives + **I**nnovation + **O**utput), which is framed around six primary outputs:

- reliability of network services and the wider system
- safety
- environmental targets
- conditions for connection to network services
- customer satisfaction
- network-related social obligations. (Ofgem 2010b)

However, this new formulation does not escape the need to ensure that the costs of meeting these objectives are accounted for, and that efficiency in both operating and

capital cost is improved. In other words, the need to set *x* cannot be avoided, but there is no completely satisfactory way of doing so given the inherent uncertainty attached to future levels of cost and income.

Some regulators have tried a benchmarking approach to determine the scope for greater efficiency, either within the relevant UK industry or by drawing on the experience of other countries. In the case of water, for example, mergers have been strictly controlled in order to maintain a satisfactory number of comparators, although the diversity of operating conditions within England and between England and other countries has limited the extent of its use. Nevertheless, such comparisons have provided evidence that Network Rail's costs are too high and that there is therefore substantial scope for a reduction in the subsidy (House of Commons Committee of Public Accounts 2011b).

The NHS tariff was originally introduced to support patient choice rather than to promote efficiency, but the way it has come to be used – to impose a downward pressure on provider costs by reducing the tariff in real terms – means that it has similar properties to the RPI–*x* tariffs in the utilities industries as they were originally introduced. The *x* has been set annually rather than for the three-to-five-year period typical for the utilities (and now eight years in the case of energy networks), and its level has been determined by what trusts have been able to achieve on average, in other words, through a form of benchmarking. This year-on-year downward pressure on prices has resulted in the acute sector having to make significant efficiency savings. However, it is clear that there are limits to applying this to one part of the health care system when some of the real efficiencies are to be had by redesigning services across organisational boundaries.

Despite these similarities, there are also important differences. Although in the case of BT (as British Telecom was rebranded in 1991) the price control formula developed some degree of complexity to take account of the expansion of products resulting from the introduction of mobile phones and the internet, it has never approached the complexity of the NHS tariff, in which there are several hundred prices for individual services (and even this number is achieved only by bundling together similar but not identical services). Furthermore, there remain a number of areas such as specialised services and community services where suitable tariffs have yet to be devised. The NHS tariff has been further complicated by the introduction of incentives in relation to specific objectives, eg, reducing emergency admissions, promoting day surgery and rewarding better quality.

As noted above, the Bill provides for Monitor and the NHS Commissioning Board to co-operate to produce the tariff, with the latter responsible for the general structure and the former charged with devising the specific tariff values. Whatever form the tariffs take, Monitor will be faced with a difficult task. The current tariff already serves a number of purposes but more are likely to be added, including treatment of capital costs (see below), the need to unbundle (to allow competition for parts of a care pathway) and to bundle tariffs to allow for the assembly of elements in to a care package, eg, for diabetic care (Hawkins 2011).

Amendments to the Bill seem set to make the task even more difficult. These require Monitor (and the NHS Commissioning Board) to have regard to the impact of variations in the range of services offered by different providers as well as the complexity of patients' treatment. These changes open the way for different prices for the same services depending on the setting in which they take place.

There is a clear need for such variation. The current method for determining the tariff assumes, input cost factors apart, that hospitals have similar cost structures, but if hospitals lose some functions then the resulting cost structure may be atypical, particularly if they are stuck with capital stock that they cannot redeploy or with private finance initiative (PFI) contracts that they cannot, except at major expense, get out of.

Thus a fixed tariff based on a national average or an average of better performers will make it harder for some hospitals to survive even if they are competitive for some services and working efficiently given the circumstances in which they are operating.

Monitor is therefore faced with an extremely difficult and complex task, partly due to the heterogeneity of the product (health care), the number of product lines (procedures, care bundles, etc) and the potential for cross-subsidy between them. The information available to support Monitor in defining the tariff is limited: for example, very little work has been done in recent years on the cost structure of hospitals as a whole, although there has been some work on individual services (2020 Delivery 2010), and, as the Audit Commission recently pointed out, the quality of cost data in hospitals is poor (Audit Commission 2011). In addition, many hospitals gain income for training and research and development, the costs of which are hard to disentangle from care provision. This means that there may be unforeseen financial externalities arising from the structure of the tariff on these other hospital functions and vice versa.

A large amount of data will be required to support the price-setting function. Although there is some data on the costs of specific hospital services from hospital reference costs, equivalent information is not available for community and primary care or mental health services, nor has it been available from the private sector. The introduction of service-line management (*see* box below) holds the potential for setting service-line budgets, but it has also exposed some of the shortcomings of the current tariff regime. For example, some essential clinical services such as maternity appear to be consistently unprofitable across trusts, pointing to a poorly constructed tariff (Foot *et al* 2011, forthcoming).

What is service-line management?

First introduced into health care in the United States in the 1980s, and later developed and championed by Monitor in England as part of its function to support good financial and performance governance in foundation trusts, service-line reporting and service-line management are one approach to informed clinical leadership that is increasingly being adopted across the hospital sector.

In service-line management, a hospital trust is divided into specialist clinical areas that are then managed as distinct operational units. Service-line reporting provides data on financial performance, activity, quality and staffing, and the service-line management structure enables clinicians and managers to plan service activities, set objectives and targets, monitor their service's financial and operational activity, and manage performance (Monitor 2009).

Source: Foot *et al* 2011, forthcoming

An alternative to setting prices at the level of each item or episode of service or for a service line is to set profit/surplus caps for foundation trusts. However, this approach would make it possible for financially strong trusts to indulge in price competition, using their financial strength to lower prices in competitive markets while retaining higher prices in those subject to less competition. If the system were to develop more integrated delivery systems with bundled payments for larger groups of patients or packages of services, then such downward pressure on prices might result in greater efficiencies and restructuring of the market in ways that have long been advocated (for example, shifting care into community settings). However, the government has all but ruled out price

competition, seeing it as posing a risk to quality, so the complexity of the tariff is likely to remain.

The intricacy of the pricing system as currently proposed is striking, and there is no precedent in the other utilities sectors. Such complexity might actually weaken the signals to providers who, faced with so many conflicting price signals for different parts of their business, may simply ignore them and absorb the risks. A clearer pricing strategy is needed that not only reflects the need to drive productivity across the sector to support more integrated care, but also the feasibility of the price-setting task and the wider incentives faced by providers.

Rate of return and financing capital

The RPI–*x* regime has been widely copied in other countries largely because of its ease of application and also because it seemed to avoid the weakness of the form of price control commonly used in US utilities, namely rate-of-return regulation. This set a return relating to capital employed, thus encouraging capital spending while offering no specific incentive to reduce operating costs. In contrast, the RPI–*x* regime provides a strong incentive to reduce costs in line with *x*, and also to outperform this level as long as the companies do not anticipate a retrospective claw-back of 'excessive' profits. Regulators are seen as taking different views on overperformance, some seeing it as an important part of how the regulatory regime should work while others are unwilling to allow significant outperformance (and the associated profits).

However, as noted above, as RPI–*x* has been developed, it has increasingly resembled rate-of-return regulation. At the time that the RPI–*x* tariffs were introduced, the main issue appeared to be the need to protect consumers from monopoly power and to promote efficiency. Over time, however, the emphasis has shifted to focusing on the need to raise capital for network expansion or quality improvement. This has been a particularly acute issue in the water industry because of its immense capital requirements, driven mainly by the need to improve quality rather than provide extra capacity. The electricity regulator has also had to allow prices to rise in order to meet both capacity and environmental objectives.

As a result, a key element in regulators' decisions has been concern about the industries' ability to raise capital and the cost of that capital. In principle, the cost of capital to a utility such as water should be low as a return is virtually guaranteed. However, as the regulator is in a position to determine profit levels, to a large degree, a regulatory risk could develop if the regulator is seen to be likely to cut future returns (eg, in the next price review) or even, as happened in the early days of regulation, make *ex post facto* adjustments to profit through a special levy. The result is a higher cost of capital than should be achievable in a utility where market risk is low.

In the NHS, there has never been any clear relationship between capital spend, costs and prices. The capital programme announced in *The NHS Plan* (Department of Health 2000) was not expected to achieve cost reductions below the then current levels, and no serious demand forecasts were made (eg, of the potential for loss of business to community or private-sector providers).

There is currently no official view about the level of investment that is likely to be required in the NHS, nor the level of demands it is likely to face. The Bill requires Monitor to take account of likely future demand for health care services, but does not specify whether Monitor itself or some other body should make the forecasts or whether it should rely on the forecasts of individual trusts; nor does the Bill identify the extent to which Monitor or the providers should take a view on future requirements for capital expenditure.

Historically, the availability and cost of capital has not been a major issue in the NHS as most capital was funded through public-sector borrowing. Private borrowing by foundation trusts has been low, and some have accumulated substantial surpluses that they can use to reinvest in capital developments. However, other factors are likely to make capital borrowing more difficult in future: the government's commitment to reducing the deficit is likely to put greater pressure on the availability of public funding; and continued downward pressure on tariffs will reduce trusts' ability to meet the revenue costs of capital borrowing (eg, through PFI).

If the tariff is pushed too far downwards, or if this is seen as likely in future years, then the risk attached to new investment will be increased, with the result that new or even replacement investment might not be viable in either the NHS or the private sector. This would make it hard for new entrants to come into the market. However, it is possible to argue that hospitals as a whole might not need to set prices at long-run marginal cost, since demand for (some of) their services is likely to fall as services are shifted to community and domestic settings. If the regulator came to this view, then the resulting prices would tend to make it even harder for new private sector entrants (who would have to cover their long-run marginal costs).

There is also the problem posed by PFI contracts. These do not allow the trusts concerned to reduce their capital costs if they lose business or if they need less capacity as a result of using what they have more efficiently. Palmer (2011) has argued that the existing treatment of capital costs, ie, a standard mark-up, makes it impossible for trusts with high PFI costs to compete. Similarly Mason *et al* (2009) have argued that, as capital costs are outside trusts' control, the tariff should be varied as far as the capital element is concerned. Continuing to expect trusts to finance capital costs from tariff will mean many hospitals with newbuild facilities getting into financial difficulties. There is therefore an urgent need for the government to develop a policy on how future capital investments will be funded in the NHS. This must balance the need for future long-term capital investments with the need to create a level playing field between providers.

Structural measures

As explained earlier, at the time of privatisation the utilities were national or regional monopolies. Structural measures were required if markets were to function. The basic strategy adopted for the promotion of competition following privatisation of the utilities was to isolate the elements of each business where competition could be created from those where it was not feasible. Thus, in the case of electricity, the national grid was hived off into the non-competitive sector, while a number of separate generation and distribution companies was created and a market developed in generation and supply. In the case of electricity generation, for example, individual generating units such as Drax were established as separate companies on a one-by-one basis to ensure there were sufficient players to form a competitive market. Similarly, BAA was required to dispose of some of its airports.

Where physical break-up was not used, eg, in the telecommunications industry, the regulator has aimed to ensure that potential competitors have access to the BT network at the same price that BT charged internally to its own service. This has required the creation of separate divisions within BT, with extensive governance arrangements to ensure the equivalent treatment of the retail interests of independent companies and BT. The regulator also took the additional step of requiring the network to be physically modified at local level (local loop unbundling) to allow competition at the local end of the business.

In the case of rail, a franchising regime was introduced for passenger services, allowing competition to provide services on specific routes. In the water industry, privatisation

led to the creation of local or regional monopolies, and the introduction of competition has been slow. Nevertheless the regulator is beginning to develop a similar approach to that used in other utilities, requiring the industry to provide accounting information on specific parts of its business so that a market might develop for the services concerned.

As already noted, a degree of competition has already been introduced within the NHS, particularly for elective care, but major services, particularly hospital-based emergency care, remain local monopolies. Current policies aimed at promoting the quality of care for stroke, trauma and other emergency services continue to push for larger units or networks of providers. There may be scope in respect of these services for competition to develop *for* the market but not *within* the market. However, this might be tricky to organise. Once specialist centres have been created and other providers decommissioned, it could prove hard to find potential alternative providers with the requisite expertise and capital. Transition costs, if a franchise were lost, might also be high.

If competition for such markets did not develop, then NHS foundation trusts would be in a position similar to that of BT, combining, within one enterprise, monopolistic and competitive services. There are several approaches to separation that could be considered for foundation trusts, ranging from presenting separate accounts to functional separation through separate management and governance arrangements, and from legal separation by establishing a subsidiary with its own board to full separation with different ownership. The approach taken in respect of BT would suggest splitting trusts up into, say, emergency, elective and diagnostic divisions with their own accounts – and possibly further into product lines using the accounting methods developed for service-line reporting. For this to be successful, a credible level playing field with other providers would have to be created in the potentially competitive markets.

Such a policy would be tricky to implement. Acute hospital services are multi-product enterprises. They are typified by a high level of fixed and joint costs, and many services are shared. This means that once the direct costs (eg, staff, consumables) of, say, an ophthalmology service are determined, the 'full' accounting cost, which includes a contribution towards overall hospital costs, is to some degree arbitrary. The problem of establishing the 'full' cost of a service already exists in hospitals using service-line management, in which an overhead for each element of the tariff or service line is calculated. Trusts will have to ensure greater transparency about the accounting costs of competitive and non-competitive businesses, and demonstrate that they are not using surpluses from one part of the business (the monopoly services) to reduce the prices they are able to charge in the other (the competitive services). If they are not allowed to cross-subsidise, there may be unforeseen consequences for services that are currently being funded this way. Their viability may be threatened, requiring action by the regulator to ensure continuity of essential services (*see* below).

Giving competitors access to facilities

A parallel route to creating competition has been the opening up of facilities to new providers, allowing them to compete nationally without the need to invest in capacity themselves.

In the case of telecommunications, as already noted, British Telecom (as it then was) was forced by the regulator to allow access to its network at a price equivalent to its own internal price and also to allow local exchanges to be modified (local loop unbundling) so that competition could develop in broadband and local calls. These changes have been generally seen as decisive for allowing competitors to enter the market. The same policy has been applied to postal services, by allowing potential competitors access to the main sorting offices. So far the provider response has been much less than that in the telecommunications industry.

The nearest comparison in the NHS are facilities that require high levels of capital investment such as expensive diagnostic equipment. Lack of access at a fair price to these so-called 'bottleneck' facilities can mean it is uneconomic for an alternative clinical service provider to enter the market, thus limiting competition. The original Health and Social Care Bill gave Monitor powers to force providers to open up access to their facilities to competitors, but this has now been dropped.

Although providers would currently be faced with some clear practical challenges in opening up their facilities and assets to be used by other service providers – for example, cross-charging, hours when the shared facilities were available and clinical governance – there is existing experience that could be drawn on. For example, the arrangements for direct access diagnostics for GPs, more novel lease arrangements with technology companies in which the equipment is owned by the company (limiting the investment risk for any single provider), and the franchise approach used by Moorfields Foundation Trust (which provides eye care to a number of London hospitals). These arrangements are currently seen as mutually beneficial, but if Moorfields or similar specialist hospitals or departments started to compete for business within other hospitals, a key issue would be the price and other conditions attached to making other hospital services such as diagnostics available.

If lack of access to some facilities with high up-front capital investment costs acts as a barrier to alternative clinical services providers (who may be able to offer higher quality at a lower cost than the NHS), then Monitor might ask the government to reconsider its decision not to give them powers in this area. If commissioning moves away from contracting with specific organisations to contracting for outcomes and clinical services across whole pathways, monopoly ownership of facilities could reduce the range of alternative providers who are able to bid. This is likely to precipitate a wider debate about the relationship between those who own and manage facilities on the one hand, and the providers of clinical services on the other.

In other sectors, technological change has opened up significant market opportunities, reducing the structural constraints on competition, eg, mobile and wireless technology in telecommunications. In health, technological change has not been dramatic, but some innovations such as telecare and new drugs mean more care can be delivered in the community or home as patients can self-manage, no longer requiring the same degree of professional care. These developments are likely to provide greater opportunities for new entrants and challenge to incumbents than are powers to open up access to existing facilities.

Promotion of entry

A third route to creating competition is the promotion of new entrants. This has not been a major feature of policy in the utilities, but in some circumstances utilities' regulators have supported the entry of new firms over and above the restructuring measures outlined above. In the case of telecommunications, for example, Mercury was helped to set up an independent network by keeping the field free of other entrants for a period of seven years. Similarly, the recent spectrum auction conducted by Ofcom was designed to help a smaller bidder, Three, to have a chance of succeeding. In the power sector, the process of breaking up the existing monopolies created opportunities for entry through the purchase of companies or specific assets such as power stations, and entry has been further encouraged through subsidies for renewable generation. In the case of rail, the franchise system for particular routes has allowed new entrants from outside the rail industry.

In the NHS, a policy designed to promote entry was implemented when contracts were let to private firms to run independent-sector treatment centres as part of the government's

policy to reduce waiting times. Prices were set above the NHS tariff and providers were paid irrespective of whether they had actually carried out the agreed number of operations (ie, they were given a volume guarantee). It was judged that without specific support the market in elective care would be regarded as too risky for new firms to enter. The special privileges attached to the first round of entrants were removed from later contracts.

The government has also encouraged commissioners to support the entry of third-sector suppliers, particularly social enterprises. As part of transforming community services, independent community-service providers were given long-term contracts in order to enable them to get established. However, the coalition government has indicated its intention to introduce an 'any qualified provider' market in community services, thus removing any preferential terms.

The revised Bill makes it clear that promotional tariffs cannot be introduced in future to support the entry of a particular type of provider, suggesting that this regulatory tool will not be available to Monitor in future. However, as the Co-operation and Competition Panel report has shown, there are risks that commissioner behaviour will create barriers to entry and limit patient choice. A critical issue is the extent to which service tendering, particularly for services that are not episodic such as care for those with chronic conditions, will limit the extent of choice in practice.

Promoting choice

For competition to be effective, users must be able to exercise choice. In some services, such as water and postal services, choice remains limited as competition has scarcely developed. In others, such as telecommunications and power, it is now extensive, partly as a result, in the former case, of new firms entering the market using technologies that were not available when British Telecom was originally privatised.

Nevertheless, regulators have found it necessary to take measures to support user choice. For example, in the case of telecommunications, the regulator encouraged the introduction of technologies that have made it easier for users to switch between providers (eliminating the need to make a separate payment to BT for line rental) and allowing them to retain their telephone numbers when they do so.

But even where switching suppliers is technically easy, the complexity of the tariff and contracts offered by some providers has proved a serious obstacle to exercising choice. In some sectors, such as rail, standard packages have been mandated to enable consumers to compare products. In addition, online sites have developed offering price comparisons for power users and support for switching, and the number of intermediaries offering advice on optimal tariffs has grown substantially. More than half the energy requirements of non-domestic users are bought this way.

Users of the gas and electricity utilities can have confidence that the product is the same whatever company supplies it. In principle, users should therefore find it easy to switch to suppliers offering a better deal. A sizeable proportion of users of power services do switch suppliers, but they do not always gain by doing so. According to Ofgem (House of Commons Energy and Climate Change Committee 2011), about 40 per cent of consumers who do switch move to an inferior deal.

Unsurprisingly, Ofgem has recently concluded that competition was being stifled 'by a combination of tariff complexity, poor supplier behaviour, and lack of transparency' (Ofgem 2011b, p 1). To deal with these issues, it proposed a series of measures including:

- price simplification
- breaking the power of the Big Six over the wholesale electricity market

- tougher enforcement and more requirements to ensure companies play straight with consumers
- reducing unfair contracting
- improving transparency. (Ofgem 2011b)

These measures appeared necessary because the regulator was forced to conclude that competition does not always act in the interests of users. For example, doorstep selling may induce changes in supplier that are of no benefit to the users concerned (Price 2005). Alternatively, users might not be able to determine which the best package for their requirements is because of the way in which information is provided about the pricing structure. Such supplier-induced complexity is generally considered to be anti-competitive.

The problem of complex pricing for consumers does not arise for NHS-funded services, which are largely free at the point of use. Consumers do face difficulties, however, in understanding the complex information on the comparative quality of hospital services. If providers promoted their services in ways that potential users found difficult to understand, the regulator may wish to intervene to ensure consumers are provided with simpler information.

The Department of Health previously required primary care trusts to raise awareness of patient choice. Patient choice is now a right in the NHS constitution and the government suggests this will form part of the mandate to the NHS Commissioning Board rather than a role for Monitor. Despite an increasing amount of information on the quality of services and websites designed to help patients compare the quality and performance of providers, the majority of patients are loyal to local hospitals even where they have an alternative provider within reasonable travel time (Dixon *et al* 2010). If competition does develop further, providers may seek to make their services more attractive by (selectively) providing more information about them. It is not clear what, if any, role Monitor will have in requiring providers to disclose information publicly or in tackling misleading marketing or advertising; nor is it clear whether providing information and data will be part of the licensing conditions for both public and private providers.

In the utilities sector, there has been a move to standardise the way services are described for ease of comparison. Increasing personalisation of services and tailoring of packages of care in the health sector is desirable, but it will make comparison of the quality and outcomes more difficult. Monitor will need to work closely with the Information Centre to ensure that standardised data on the quality and costs of services are available for all types of provider regardless of their ownership status. 'Commercial in confidence' must not be used as a reason for restricting data availability.

Funding unprofitable services

The regulated industries all retain some of the social obligations of their nationalised predecessors, typically in the form of an obligation to supply in all parts of the country or region covered by their licence, and to all users at the same prices (albeit modified in some high-cost areas) for a given level or quality of service. This has meant that profitable services have been used to subsidise non-profitable ones both between geographic areas and between different types of customer. Only in the case of postal services is it the primary duty of the regulator to maintain a universal service, although other regulators do have comparable obligations for some services (eg, BT telephone boxes).

As Table 1 (*see* p 13) shows, industries are subject to different social obligations. For example, power suppliers are required by their licence to protect vulnerable users. The regulator Ofgem has produced a social action strategy (Ofgem 2011a), setting out how it

intends to ensure the interests of those on low incomes, disabled consumers and those of pensionable age, together with how it sees the broader obligation to reduce fuel poverty, as required by the Warm Homes and Energy Conservation Act 2000.

In the case of rail, a cross-subsidy regime was in force prior to the Second World War, but the rise of road transport undermined it. The initial response was to free British Rail from pricing restraints, eg, to allow discriminatory pricing. After the Beeching report in the 1960s, a system was introduced in which the government decided whether to pay to keep specific lines or services open. That regime was later replaced when British Rail was privatised between 1994 and 1997. The franchising regime then introduced allows some degree of competition, ie, *for* the market not *in* the market. It is designed as a subsidy minimisation device, ie, the best bids (other things being equal) are those requiring least subsidy for a given pattern and level of service or where services are profitable, offering the maximum return to the taxpayer. Service obligations, eg, service frequencies, opening hours of ticket offices, are built into the franchise.

The question arises in the health sector as to who will pay to maintain universal access in, for example, rural areas, where some services might not be economically viable. As noted above, different ways of financing such services are in use in the utilities sector – the prevalent cross-subsidy financed by other customers of the licensed entity (water, rail, postal services, telecommunications) and the less common *ad hoc* subsidy financed by taxpayers (rail).

Neither of these methods seems suitable for a situation in which local commissioners seek to preserve local services when these could be provided more cost-effectively in other locations. It appears from current proposals that commissioners will be required to pay this additional cost above the national tariff. Presumably this would in time be reflected in higher allocations to these commissioners. Another option would be a levy on all commissioners by Monitor to fund these subsidies.

A similar issue arises where service viability is threatened because of a failure to meet quality standards. The CQC has powers to suspend services if they fail to satisfy minimum safety and quality standards, but if more money is needed in order to bring care back up to the required standards, it is not clear who should bear that cost.

Managing failure and insolvency and ensuring continuity of access

As in other markets, utility providers who continue to run unprofitable services and do not have access to equity to refinance their business could become insolvent. However, given the importance of these services and the lack of alternative suppliers in some cases, special arrangements exist to ensure continuity of access. In the case of rail, for example, withdrawal by National Express from the East Coast mainline franchise was met by the establishment of a state company to continue the service (House of Commons Committee of Public Accounts 2011a), as a result of which there has been no loss of service.

In the case of energy, some retail entrants failed, but their customers were taken on by other retailers and customers' supply was not affected. In the case of Independent Energy (a failing generator) the company was bought by a competitor and again supply was not interrupted. However, in a number of cases equity investors did lose money when their companies failed, including Railtrack, Welsh Water, Drax, British Energy and Eastern Electricity. The existence of equity provides a buffer that facilitates such transitions.

In health care, the need to ensure service continuity if a foundation trust becomes unsustainable or a large private provider of health or social care becomes insolvent is equally important. The failure of the care home provider Southern Cross underlines the need to anticipate the possibility of financial failure. The same issues could arise in health

care if a private health care provider or social enterprise gained a dominant position in a regional market, or reached a certain size in the national market, making it 'too big to fail'.

The previous government introduced a special administration regime to deal with insolvent trusts. The coalition has indicated that it intends to strengthen this regime, as well as introducing new provisions that will apply to the private sector (Department of Health 2011b). 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 becoming unsustainable. In the event that the provider cannot be rescued, then a continuity administrator will be appointed that would be responsible for recommendations on how to secure essential services as identified by the commissioner(s). Monitor will have the responsibility 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 operating the regime.

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 health special administration regime will apply. These providers would have additional conditions attached to their licence from Monitor. The details of this will be set out in secondary legislation. This would, 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.

To be in a position to intervene before a foundation trust becomes unsustainable, Monitor will have to assess provider risk. Other sectors have sought to develop viability monitoring systems but, as recent events in the financial services sector have shown, these do not always work.

Another concept in regulation in other sectors is the 'financiability' of undertakings, which means that they have to have a minimum credit rating in order to be able to raise sufficient equity to remain a going concern and prevent insolvency. This supports the case for Monitor to have the powers to exercise proactive financial oversight of the kind it currently has over foundation trusts at the time of authorisation and on a continuing basis, particularly when providers adopt high-risk business plans that make them vulnerable to downturns in business, or when providers have a certain level of market penetration (as proposed in the amended Bill). Such an idea was suggested by Lewis and colleagues:

> *Any extension of economic regulation, for example monitoring internal financial viability beyond existing generic insolvency regulation to independent providers, would be a significant development. However, as (and if) the NHS market matures, with greater penetration of independent providers and therefore more mutual dependence, such a proposition may become more credible.*
>
> (Lewis *et al* 2006, p 53)

However, it is important that this does not encourage irresponsible behaviour on the part of the providers. If they adopt a high-risk business plan without adequate financial or other contingency, then they should suffer the consequences if it fails. Therefore, as part of such a regime, there could be a requirement for providers to provide funds up front, ie, when they win a contract, which could be used in the event of financial failure to provide a breathing space before a financial rescue or takeover can be arranged. This is similar to a performance bond issued by an insurance company or bank to guarantee

completion of a project by a contractor. Such a bond could be required by Monitor so that in the event of the provider becoming insolvent, the value of the bond could be used to ensure continuity of services. The provider would have to meet the costs of the premiums.

There is also a need to develop an independent banking function for the NHS. While the NHS Bank remains within the Department of Health, the government will continue to be able to provide loans to trusts on favourable terms, protecting them from becoming unsustainable. Where there is a mix of private investment and public subsidy, as there is in PFI hospitals and local improvement finance trust (LIFT) projects in the community, there is a risk that if the state reneges on an agreement it leaves the private investors without any options for recovering the value of their investments. The consequence would be increasing costs of capital in future.

What can we learn from economic regulators in the health care sectors of other countries?

All countries regulate their health care systems, but the means they use differ widely, reflecting different ownership structures, histories and values. Until now, economic regulation has not been widely applied in the health sector, despite the existence of natural monopolies. The government has historically chosen to operate the health system largely within the public or statutory sector as was previously the case with utilities while they were nationalised.

Several countries have experimented with internal or quasi-markets similar to the regime introduced into the NHS in the 1990s, which have sought to create the incentives of a market but with the majority of services continuing to be publicly funded and provided. The increased involvement of the private sector as a competitor for publicly funded services has, in effect, created a 'real' market, subject to competition law. In other countries, competition between public and private companies in the market for health insurance has also meant that the insurers as well as the providers are subject to competition law.

Where countries have allowed or encouraged a market in health care services to develop, regulation is focused on ensuring the effective functioning of that market. Here we look at two countries, the United States and The Netherlands, where this form of regulation is most advanced. In the United States, health care is covered by the Federal Trade Commission, which is a general competition authority, and the Department of Justice (Johnson 2010), whereas in The Netherlands there is a sector-specific competition authority.

The Netherlands established a sector-specific regulator in health in 2006, superseding the National Health Tariffs Authority and the Supervisory Board for Health Care Insurance. Known as the Healthcare Authority (NZa), it is broadly tasked with managing:

- competition
- prices and budgets
- transparency in health care (*see* box opposite).

The NZa works with the Healthcare and Liberal Professions department of the Dutch Competition Authority (NMa) in a number of ways. The NZa has authority over the NMa in relation to enforcement of specific actions, even if in disagreement with the NMa. However, with regard to mergers of health care organisations, the NZa gives its opinion on the impact the merger will have on affordability, accessibility and quality in the health

care market, together with feedback from the Inspection for Health Care, to the NMa, which ultimately enforces the merger control provisions of the Competition Act.

The minister for health cannot intervene in or overrule decisions by the NZa in individual cases, thus retaining a separation between health care policy and health care regulation. The minister is, however, able to guide the issues that the NZa should focus on, and can also veto any of the NZa's general rules, or implementation of any of these rules.

There has, however, been some confusion within the industry about whether collaborative efforts are or are not anti-competitive, and an assumption by providers that less

Summary of regulation by the Healthcare Authority in The Netherlands

The mission statement for the Dutch Healthcare Authority reads:

> *The NZa creates and monitors properly functioning healthcare markets. The interests of the consumers are central in the performance of these tasks. Efficiency, both in the short and long term, market transparency, freedom of choice, access to healthcare and quality are guaranteed. This gives the consumer the best value for his or her health care euros.*
>
> (NZa 2011)

It interacts with the health care market in The Netherlands in many ways, as set out in the Healthcare Market Regulation Act, namely:

- supervises and stimulates competition processes (including calculating and setting the tariff, and improving a level playing field for competition among providers)
- supervises compliance of health insurers with the Health Insurance Act
- supervises the Exceptional Medical Expenses Act
- advises, for example, on the geographical market definition in health care and on merger control
- sets the rules, for example, on the publication of information by health care providers.

As the NZa website explains:

> *The array of legal instruments available offers the NZa options for establishing general conditions for the healthcare markets such as performance descriptions, cost allocation principles, smart price ceilings and supervisory rules concerning, for instance, deceptive advertising. In addition, the NZa can take action in individual cases, such as in the case of a provider that has a position of significant power on the market, if the competitive conditions are distorted.*
>
> (NZa 2011)

The NZa seeks to balance the use of the tools available to it to provide proportional and liberal supervision of the market, allowing for a degree of individual freedom among providers (NZa 2008). It applies a risk analysis model to analyse how much supervision and market development is needed in the sector.

A diagnosis-related group system called diagnosis and treatment combinations has been in place since before the inception of the NZa. Roughly 34 per cent of these were freely negotiable between insurers and providers on price, quality and volume in 2010. The NZa establishes the prices for the other 66 per cent. Insurers and providers can then negotiate on volume and quality considerations.

collaboration is allowed than is actually legislated against. In 2010, the NMa published guidance for the health care industry that seeks to clarify further the implications of the provisions of the Dutch Competition Act for collaboration and sets out more clearly the distinct roles and responsibilities of the NMa and the NZa (European Commission 2010).

In contrast, the health care market in the United States is subject to competition legislation that is applicable across all sectors of the economy. Nevertheless, the application of the legislation has been tempered by concerns about the potential risks to integration and co-operation from a heavy-handed application of competition law. The US health care system has examples of highly integrated delivery systems, and during the 1980s there was growth in integrated provider associations – networks of physicians that independently contract with managed care organisations and employers. Today there is growing interest in developing accountable care organisations, which bring together hospitals and medical groups in order to take collective clinical as well as financial responsibility (Crosson 2011).

The two US federal agencies responsible for enforcing anti-competitive (or anti-trust) law (the Department of Justice and the Federal Trade Commission, often referred to as the agencies) actually have a policy of encouraging integration where it would benefit consumers. They are then responsible for ensuring that integration between providers and hospitals does improve quality and efficiencies, and does not subvert the anti-trust laws and principles. More specifically: 'If integration is used as a pretext for price collusion between competitors or to solidify a dominant position in the market, rather than to create realizable benefits for consumers, the integration will not be in line with general antitrust principles' (Johnson 2010, p 20). Price-fixing of any kind is allowed only in circumstances where sufficient integration between providers has been secured and demonstrated. Hawkins (2011, p 13) has set out some of the key differences between the US system of regulation and that proposed in England.

In both the United States and The Netherlands, there are insights to be drawn about striking the right balance between levels of competition and integration within health care. Both countries have acknowledged that there are 'good' types of integration and competition within health care, and that integration can be a positive feature of a health care market. Not all types of integration are anti-competitive; indeed, the US experience suggests many benefits from proactively developing integrated health care systems. However, reflecting on the experiences of these countries also suggests that it is difficult to define and judge whether integration is anti-competitive. The box opposite provides examples of the sort of assessments carried out by the US Federal Trade Commission when assessing whether the proposal for a jointly contracted clinical integration plan by a physician group (integrated care agency or other arrangement) is anti-competitive.

The experience in the United States suggests that it is possible for competition law to be applied in a way that can also foster integration where this is in the interests of the public and patients. The key test in future for those seeking to develop more integrated approaches to health care delivery will be whether they have evidence to demonstrate the benefits. To date, the Co-operation and Competition Panel has found the NHS to be weak in this regard (personal communication).

In some countries, the functions of economic regulation are carried out by government, in others, such as the United States, by general competition authorities, or a sector-specific regulator that has other powers in addition to those relating to competition, as in The Netherlands and is proposed in England.

There may be some advantages in having a sector regulator rather than relying solely on the competition authorities to regulate the market in health care. First, a sector regulator will have greater expertise in health care and might therefore be able to ensure that

Examples of assessments by the US Federal Trade Commission of clinically integrated services

- What do physicians plan to do together from a clinical standpoint?
- How are these activities designed to improve quality of care, reduce the cost of care or produce other efficiencies?
- How will the program foster interdependence among physician participants?
- How will physicians be motivated collectively to achieve the program's goals?
- How significant will the physicians' investment in the program be?
- How will performance be monitored and measured?
- Why is joint price negotiation reasonably necessary to achieve the program's intended goals?
- What are the likely competitive effects of joint negotiation?

Source: Johnson 2010, p 11

competition law is applied appropriately. Second, experience from other sectors suggests that interventions by the competition authorities are rare when there is a sector regulator. Thus the sector regulator, by acting itself, could protect the NHS from being subject to investigation and intervention by the competition authorities. Concern has been expressed at the application of competition law to health care services in England, and having this done by a sector-specific regulator could make it more politically acceptable. However, the proposal to bring these functions into a single independent body appears to have heightened opposition, although some of these functions – such as price-setting, failure and compliance with the principles and rules for co-operation and competition – existed already within the Department of Health.

The examples of regulation in The Netherlands and the United States suggest that it will be essential for the relationship between Monitor, the OFT and the Competition Commission to be unambiguous, and that where there are differences of opinion – either in relation to individual complaints, appropriate enforcement actions or mergers – it is clear how these are to be resolved and which body has final authority.

It is also important that Monitor and the Department of Health provide clear advice and guidance to providers in both the public and private sectors with regard to what forms of collaboration and integration are likely to be permitted and how these should be formed in order not to be judged anti-competitive. There is otherwise a danger, as in The Netherlands, that providers will act cautiously even when partnerships and joint ventures could be in the interests of patients and the public.

Experience in the United States suggests that it should be possible to balance competition and integration, and that competition authorities are able to adapt their approach to enable integrated models of care that achieve efficiencies in the cost and quality of care provided to patients to flourish. As Hawkins (2011) argues, the barriers often lie elsewhere in the system, for example, as a result of financial incentives or the type of contracts let by commissioners.

Implications for economic regulation in health care

This review of the experience of other economic regulators has highlighted a number of issues that need to be addressed by those responsible for designing and implementing the legal duties, guidance and powers of Monitor as the regulator for the health care sector. In this section, we draw out some of the implications of our findings for the development of economic regulation in health care in England.

Policy objectives and framework

It is important that the objectives of Monitor are clear and simple, and align with the mandate for the NHS Commissioning Board and the NHS Outcomes Framework. Monitor currently has a large number of objectives and some of them appear to be in tension with those pursued by other bodies. Experience in other sectors suggests that setting too many policy priorities risks confusing the regulator about its primary objectives, reducing its effectiveness. The government might need to consider reducing the number of objectives.

Other regulators have found that when new objectives have been added, they have sometimes been in conflict with existing objectives, causing the regulators to seek guidance from the government on how to handle this problem. The government might need to give clearer guidance to Monitor on the relative importance of its many objectives, and the factors or considerations that it must take account of in order to enable it to make appropriate trade-offs.

Regulation in health care will need to evolve in response to changing circumstances, technologies and the market structure. Currently, Monitor's objectives are set in primary legislation, and so will be difficult to change. The government should consider whether to put the objectives into secondary guidance, together with a clear process for agreeing to changes in the objectives with the Department of Health. The government needs to clarify how often it will review the objectives, in order to protect the regulator from political whim. The Department for Business, Innovation and Skills principles have committed to this occurring once per parliament for other regulators.

Form and content of ministerial guidance

The government needs to be clear about whether it intends Monitor to act as an independent economic regulator with limited ministerial guidance, or whether it sees it acting in pursuance of policy objectives. This role has become confused in the case of other regulators whose roles and objectives have been added to, extending their remit beyond the earlier scope of regulating competition in the market. There is a risk that Monitor's independence will not be sufficient to protect it from ministerial interference given the political interest in decisions about reconfiguration and failure.

As we have argued elsewhere (Imison 2011), there are likely to be benefits from depoliticising the process of decision-making. We are concerned that the right of the Secretary of State to veto plans for continuing access to services in the case of an unsustainable provider will stop service changes that are in the interests of patients and taxpayers being made. The Department of Health might need to follow the lead of the Department of Energy and Climate Change in setting out the respective roles of the regulator and the department.

Duties and powers of the economic regulator

In line with other regulators' duties to consumers, the primary duties of Monitor are to protect the interests of patients. The more proactive stance previously suggested by the duty to promote competition where appropriate has been removed and replaced with a duty to tackle anti-competitive behaviour, suggesting a more reactive approach. It is not clear whether Monitor could still intervene proactively in the market to tackle monopoly abuses through regulation or to remove barriers to competition, although its powers in respect of opening up access to facilities have been removed.

Despite the changes in the form of wording of Monitor's duties in the Bill, Monitor will have some latitude to decide how interventionist it is in the market. It will be important for Monitor to send clear, early signals about the approach it intends to take, particularly with regard to the arrangements for developing more integrated models of care. If they are subsequently deemed to be problematic, they will take a great deal of time and resources to undo. The experience of other countries suggests that the regulator should issue clear advice to providers to explain what will and will not be tolerated, in order to create a permissive environment in which integrated care can flourish.

Relationships of the economic regulator with other regulators and related agencies

The addition of Monitor's powers as an economic regulator adds to an already crowded pitch. Monitor will have to establish clear roles and relationships with NICE, the Commissioning Board, CQC, HealthWatch and the Information Centre in order to do its job effectively. There needs to be a clear process for resolving conflicts between Monitor and other bodies such as the NHS Commissioning Board, NICE and the CQC. Otherwise, there will be a danger that the regulator will have to resort to the government to resolve these issues. Such intervention defeats one of the objectives of the establishment of an independent regulator – depoliticising decision-making.

The legislation is currently written so that Monitor, the Commissioning Board and CQC will have to resolve these issues between themselves. However, this could result in a stalemate, with regulators having to resort to arbitration to resolve disputes. The government needs to provide greater clarity on how CQC, Monitor and the NHS Commissioning Board will work together to ensure their objectives are aligned.

Expertise

Monitor is being established with a large budget, with annual running costs estimated at £82 million according to the latest impact assessment (Department of Health 2011a) and a large staff of some 500 people. It has a wide range of powers under the Health and Social Care Bill, being responsible for price-setting, competition, licensing providers, managing failure, ensuring continuity of access to services and, under the amended Bill, providing ongoing oversight of foundation trusts. These are significant and wide-ranging powers, and will require skills and expertise not currently found within the NHS.

Although the regulator will need to recruit staff with an understanding of the health sector, the approach and relationship between the regulator and providers is fundamentally different from that among existing NHS organisations, so Monitor will therefore have to recruit people with experience of economic regulation in other sectors.

The price-setting task Monitor faces is also of a different order from that in any other sector where the simpler RPI–*x* or rate of return has been used. Other regulators employ a significant number of sector specialist economists (many of which they have trained). These are simply not available in significant numbers in the NHS or Department of Health.

Accountability of the economic regulator

Along with other sector regulators, Monitor will continue to be accountable to parliament. However, scrutiny by a parliamentary committee has been found to be unsatisfactory, partly because of a lack of objective performance measures against which the performance of regulators can be judged. It is therefore important that Monitor's annual report is sufficiently detailed to allow the performance of the regulator to be judged in relation to its remit as set out in the Bill, the mandate and its own operational objectives.

The revised Bill now includes provisions for the Secretary of State to report on Monitor's performance (along with that of other bodies), but his or her powers of intervention are (rightly) limited. There might need to be a stronger role for the National Audit Office in assessing the performance of the regulator.

Another approach to accountability used in the other sectors is transparency and a strong consumer voice (*see* below).

Regulatory style and strategy

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 regulation will stifle innovation and integration. It is important that regulation creates a permissive environment rather than locking in current providers and ways of providing services. Whether economic regulation in health care will deliver benefits will depend partly on whether Monitor adopts a more punitive or facilitative approach to regulation. A standards-based approach could minimise risk, but comes at a high cost because it encourages risk-aversion and therefore limits innovation. On the other hand, an incentives-based approach could be more conducive to innovation, but is also higher risk.

The current proposals appear to imply that Monitor will police offences, stepping in to act, and presumably punish, when providers referred to them for misbehaving (ie, acting anti-competitively) are found guilty. There is a risk that providers, not wanting to fall foul of the regulator, fail to innovate, alter current service configurations or establish models of integrated care. It is important that Monitor (or the Co-operation and Competition Panel within it) issues clear guidance for providers wishing to partner, collaborate or integrate so as to ensure that such arrangements are in the public interest; it should also make clear the level of evidence that it would require to be demonstrated.

Monitor should adopt a more facilitative approach, encouraging providers to take risks and innovate.

Regulatory tools and incentives

The utilities' regulators have employed a wide range of regulatory tools and incentives, as this review has shown. Although not all of these are likely to be applicable in the health sector, many of them are available to Monitor. This review suggests that they will need to be modified from the approach currently envisaged. For example, it is striking

how complex the pricing system proposed for health care is in comparison with that employed in other sectors. The government needs to develop a clearer pricing strategy that recognises the wider incentives faced by providers and the feasibility of the task it has set Monitor with the NHS Commissioning Board. There is also an urgent need for the government to develop a policy on how future capital investments will be funded in the NHS. This needs to balance the need for future long-term capital investments with the need to create a level playing field for providers. Recent concerns about the impact of PFI repayments on the financial sustainability of providers reflects the lack of a clear approach to capital financing. There might need to be additional funding for those organisations with higher capital costs during the transition.

The approaches to market-shaping adopted by other regulators could be challenging in health care, particularly in acute hospital services, which are multi-product enterprises. Trusts will have to ensure greater transparency of accounting costs for these businesses and demonstrate that they are not using surpluses from one part of the business (the monopoly services) to undercut the prices they are able to charge in the other (the competitive services). This is likely to have unintended consequences and could threaten the viability of some services.

Critical to competition in other sectors is removing bottlenecks by opening up facilities. The government dropped these powers from the original Bill. There would clearly currently be some practical challenges for providers in opening up their facilities and assets to be used by other service providers, but if lack of access to some facilities with high up-front capital investment costs acts as a barrier to alternative clinical service providers, then Monitor might need to ask the government to reconsider its decision not to give them powers in this area. This is likely to precipitate a further debate about the relationship between those who own and manage facilities and the providers of clinical services.

The need to ensure service continuity if a provider becomes insolvent is as important in health care as it is in water or energy supply. An essential role for Monitor will be to ensure continuity of access to essential services. It must strike a balance between maintaining access to essential services and avoiding subsidising inefficient or poor-quality providers. Monitor will be able to intervene pro-actively to try to forestall potential failure during a period of 'distress'. 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. Clinical and financial failures are often closely linked, so it will be essential for Monitor and the CQC to work closely together to identify and resolve problems before they reach crisis point.

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. In the case of private sector providers of essential services this will require Monitor to establish the financial sustainability or credit worthiness of the business.

The government has made clear its intention to introduce a more transparent process for restructuring unsustainable providers than existed in the past. However, while the NHS Bank remains within the Department of Health, the government will continue to be able to provide loans to trusts on favourable terms, protecting them from becoming unsustainable. There needs to be further consideration of an independent banking function for the NHS, and also how private investments will be handled in the case of failure.

Engagement with providers and consumers

Monitor needs to ensure it listens to consumers (patients) and the public (taxpayers), but also that it works with providers. If regulation is to be effective, providers need to be involved in the design of regulation. Other industries have only a small number of providers with which the regulator needs to interact, whereas the health care sector is incredibly diverse and fragmented, suggesting that there might need to be an open process of policy development with technical underpinning, such as that used by Ofgem.

However, the regulator must also 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 taxpayers and patients) to ensure continuity of services.

HealthWatch England needs to act as a consumer champion and learn from the experience of Consumer Focus to ensure that Monitor and the CQC operate effectively in the interests of the public and patients. It 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.

It is not clear whether the revised requirement to respond to HealthWatch will be sufficient to ensure that Monitor has a strong consumer focus. It might need to consider having a citizens' panel akin to that in NICE to establish some of the criteria on which it will make decisions that cannot be made purely on the basis of technical advice.

Information regime

The regulator will have a significant need for information in order to fulfil its functions. The complexity of price-setting suggests a requirement for detailed cost information from a range of providers in order to set tariffs and make any necessary adjustments to the tariff.

Other regulators have also played a role in ensuring that consumers have sufficient information. Monitor will need to work closely with the Information Centre to ensure that standardised data on the quality and costs of services are available for all types of provider regardless of their ownership status. 'Commercial in confidence' must not be used as a reason for restricting data availability.

Conclusion

The market in health services is heterogeneous. The challenge facing the regulator will be to determine when competition is 'appropriate'. In health care, as in other sectors, there are some services that are natural monopolies and others where competition may bring benefits. There is almost no evidence to guide this at present, although there are some ideas about how far different sectors in health care lend themselves to competition (Dash and Meredith 2010).

Monitor will need to develop a nuanced approach, balancing its proactive intervention powers to remedy market failures and its concurrent powers with the competition authorities. What is clear from the review here is that regulation will evolve, taking time to develop. As the utilities' market has matured, regulation has shifted from a more proactive approach (breaking up monopolies) to a more reactive one (ensuring that competition works effectively).

Although there are some wholesale markets and others where brokers and intermediaries play a key role, such as financial services, there are no parallels in other sectors with the role of commissioners in health care. It is not clear whether commissioners or Monitor will ultimately shape the market in health services, and the government must clarify which of these scenarios it anticipates. This remains an inherent tension in the government's reforms, and the outcome will partly depend on the balance between those services that are required to be open to any qualified provider, and those that commissioners choose to award through a process of tendering.

There are also significant costs involved in introducing economic regulation, as reflected in the size of Monitor's budget, as well as indirect costs to providers. The performance of Monitor and the effectiveness of its interventions needs to be carefully weighed against the harm caused by the market failures it seeks to address. The real test will be whether it delivers benefits that outweigh its direct and indirect costs. In the past, there was an expectation that creating the scope for competition would diminish the need for intervention and regulation, but this has not always been the case. Indeed, there is a risk that regulation adds to existing mechanisms for shaping the behaviour of providers, such as commissioning and performance management.

The task faced by Monitor should not be underestimated. It is far greater than that faced by regulators in the other sectors because of the heterogeneity of the product (health services), the number and size of health care organisations in the market, and the lack of information on costs. The government needs to be clear about the objectives and outcomes it expects from regulation, but it must also not expect too much. As Stephen Littlechild, one of the pioneers of utility regulation, put it, reflecting on the experience of the United Kingdom and elsewhere over the previous two decades: 'The "right solutions" seem increasingly elusive in the face of imperfect knowledge and uncertainty about the future' (Littlechild 2008, p 3).

There is a real risk of regulatory failure. First, there are practical challenges to overcome in the short term to enable Monitor to take up these new responsibilities effectively – for example, hiring sufficient staff with the skills and expertise needed. Second, there are technical challenges, 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 challenging. Third, Monitor is likely to face political challenges as a regulator given its role in ensuring continuity of services and the implications for local service configurations. The government needs to be clear how much independence it wants to grant Monitor.

Fundamentally, the government must decide if it believes independent regulation can deliver the objectives it wants for the NHS – improved outcomes and increased efficiency. Although competition does seem to offer some modest benefits, it is by no means clear that it will deliver improvements on the scale required. As this review has demonstrated, economic regulation has been challenging to implement in other sectors. Monitor has been set a formidable task with little precedent and supporting analysis, so the risks of failure are considerable. It would be unwise to expect too much too quickly from the introduction of a sector regulator in health care. It is likely that other drivers, such as commissioning and performance monitoring, will play an important role for some time to come.

Appendix 1 Brief profiles of the key utility regulators

Water

The Water Services Regulation Authority (Ofwat) was established in 1989 on the privatisation of the 10 regional water authorities created by the Water Act 1973. These took over control of the water and sewerage services that local authorities had previously been supplying. The privatised companies have a virtual monopoly of supply within their designated areas.

Ofwat is primarily an economic regulator. Responsibility for environmental regulation lies with the Environment Agency, and for drinking water quality with the Drinking Water Inspectorate.

Telecommunications

The Office of Telecommunications (Oftel) was established by the Telecommunications Act 1984, which abolished BT's exclusive right to supply services. It oversaw the initial steps towards liberalisation of the UK telecommunications market, of which the most important step was the set of measures associated with local loop unbundling, making it possible for new entrants to compete without the need to build networks of their own at local level and to compete on equal terms with BT's own services.

The other key change was the development of mobile telephony, which allowed new providers to enter the market without needing to invest in new infrastructure. There are now four large mobile networks in the United Kingdom, plus more than 30 firms offering virtual network services. There are some 20–30 competitors in the fixed-line market.

In 2003, subsequent to the Communications Act 2003, the Office of Communications (Ofcom) took over responsibility for the duties that had previously been undertaken by five regulatory bodies:

- Oftel
- the Broadcasting Standards Commission
- the Independent Television Commission
- the Radio Authority
- the Radiocommunications Agency.

In 2011 it took on responsibility from Postcomm for regulation of postal services.

Power

The current regulator, Ofgem, was formed by the merger in 2000 of the Office of Electricity Regulation and the Office of Gas Supply.

At the time of privatisation in 1986, British Gas and regional electricity companies enjoyed monopoly positions. By the end of the 1990s, the gas and electricity markets had been opened up to competition, although the transmission and distribution networks remain monopolies and therefore subject to a price-control regime.

There are now eight distribution companies, some of which have changed hands a number of times since privatisation. There are about 40 generating companies.

Rail

In 2004, the Office of Rail Regulation (ORR) replaced the Rail Regulator (established in 1993) under the Railways and Transport Safety Act 2003. The ORR holds concurrent powers with the Office of Fair Trading for consideration of competition issues on the railways.

The ORR has a central role in determining access charges and in vetting applicants that wish to provide new (non-subsidised) services. It is also the regulator for economic and health and safety issues.

The rail industry consists of a track and infrastructure provider, Network Rail, which has a monopoly position, train-operating companies, and equipment-leasing companies.

There are about 24 passenger train operators in the United Kingdom as a whole, and a small number of freight operators, whose main competition comes from road transport. Competition in passenger services is mainly for the market at the point when franchises are awarded by the Department of Transport for specific routes.

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