



# Protecting and Promoting Patients' Interests: *the role of Sector Regulation*

# About this document

1. The purpose of this document is to provide briefing for Peers on the Government's proposals for sector regulation in the NHS, as set out in Part 3 of the Health and Social Care Bill (the Bill). This document comprises of three sections:
  - **Section A – Rationale for Sector Regulation in the NHS:** this section sets out our overarching aims and key components of our strategy for improvement in the NHS. This is important context for our proposals to develop Monitor's role as sector regulator.
  - **Section B – Monitor's role and functions:** this section describes our proposed role for Monitor, as sector regulator, in terms of its duties and functions and its relationships with the Care Quality Commission and NHS Commissioning Board.
2. Further detail on a number of issues is set out in the Annexes, including:
  - Annex 1 – Monitor and the NHS Commissioning Board's roles in pricing
  - Annex 2 – Key amendments to Part 3 in the House of Commons.

# Section A – Rationale for Sector Regulation in the NHS

## Aims – What are we seeking to achieve?

3. To drive substantial improvements in health outcomes, quality of care and productivity in the NHS to:
  - care for an ageing population;
  - manage the increased prevalence of chronic disease; and,
  - manage the rising cost of healthcare technologies (eg. drugs and equipment).

There is consensus that this can only be achieved by improving public health, empowering patients to take more control of their care and through innovation in the way healthcare services are delivered, particularly for patients with long-term conditions and for older people.<sup>1</sup>

## Strategy – How do we propose to achieve these aims?

4. To put patients and clinicians at the heart of decision-making and to strengthen and align incentives for providers to improve services:
  - **We will empower local clinicians to decide how best to meet the needs of their communities, by establishing Clinical Commissioning Groups** that will control the majority of NHS spending and would take the lead in arranging

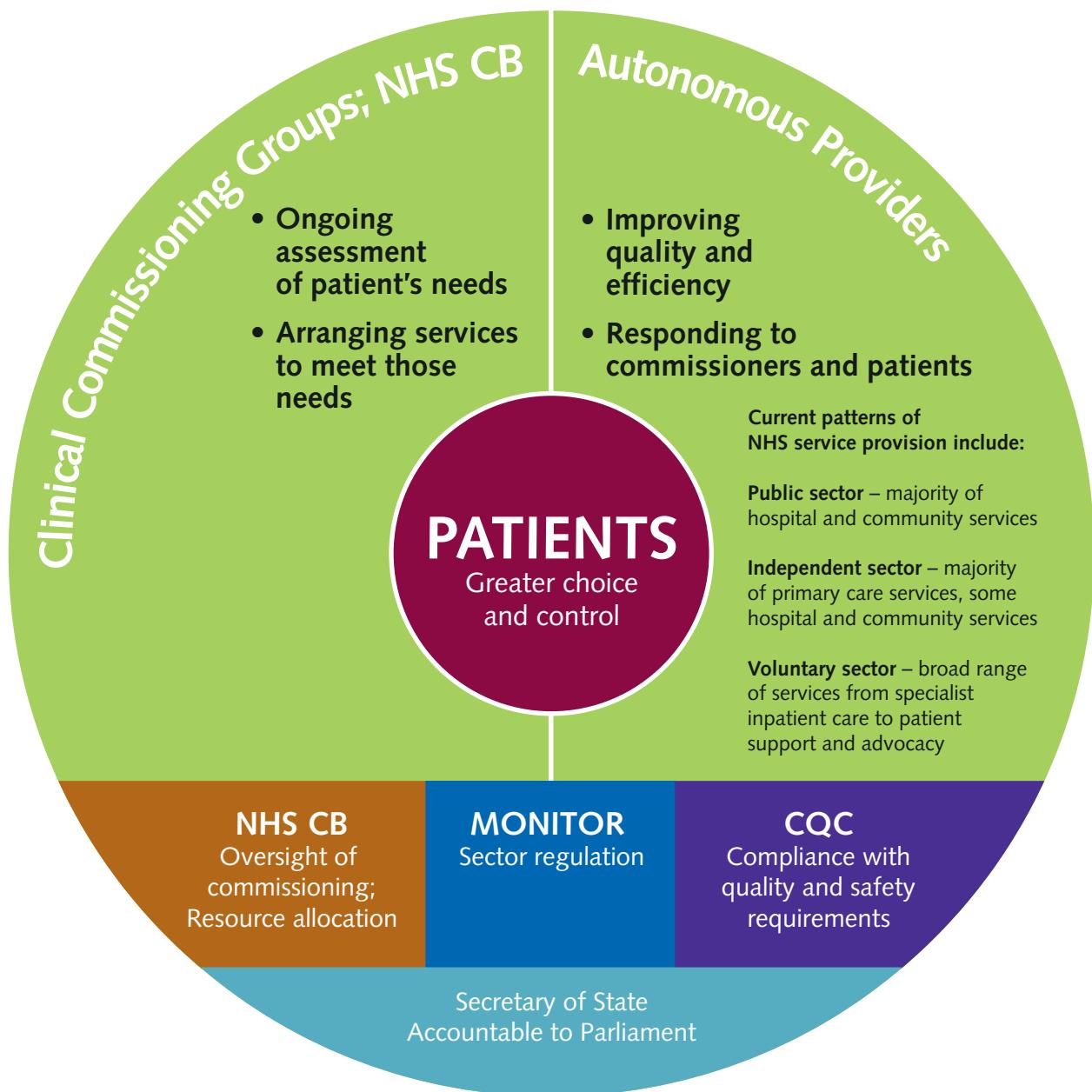
the provision of NHS services. The NHS Commissioning Board would oversee the work of Clinical Commissioning Groups and would have an overarching duty to secure improvements in quality of services in line with a 'mandate' from the Secretary of State<sup>2</sup>;

- **Local Health and Well-Being Boards would work in partnership with Clinical Commissioning Groups** to ensure that NHS services best reflected local needs and improved integration between health and social care. They would also have a key role in contributing to assessments of how well commissioners were discharging their duties;
- **Patients would have greater choice and control** over their care and treatment ("no decision about me, without me");
- **Providers would have greater freedom and responsibility** to respond to patient preferences and to redesign their services to reflect commissioning priorities; and,
- **Robust sector regulation would establish clear standards and rules to protect patients' interests** in the provision of NHS services; strengthen incentives for providers to improve the quality of the services they provide; and, secure continuity of services where necessary.

<sup>1</sup> Department of Health (2008) Engagement Analysis: NHS next stage review. What we heard from the 'Our NHS, our future' process.

<sup>2</sup> Department of Health (2011) Developing clinical commissioning groups: Towards authorisation.

**Figure 1 – Commissioning and provision of NHS services would operate within a framework of regulation to protect patients' and taxpayers' interests\***



\*'NHS CB' = NHS Commissioning Board; 'CQC' = Care Quality Commission

## NHS services would continue to be delivered by a plurality of providers

5. NHS services will continue to be commissioned from a plurality of providers working within the principles and values enshrined under the NHS Constitution.<sup>3</sup> For the first time, this would be underpinned by a comprehensive regulatory framework that would be applicable to all types of provider.
6. Effective regulation in the NHS is necessary to protect patients' interests, for example, by ensuring compliance with essential quality requirements, securing continuity of services and preventing abuses by powerful providers. Competition also has a role to play, as a tool for commissioners, in driving innovation and improvement in services and increasing patient choice. However, these are *means* not ends in themselves.
7. Our proposed approach to strengthening sector regulation is set out in Part 3 of the Bill and draw upon evidence as to the benefits of regulation and competition in public service provision, both within the UK and internationally.<sup>4</sup> NHS services would be commissioned and provided within a specific framework of rules and regulations developed explicitly to meet social and economic objectives. This contrasts strongly with the concept of a 'free market'.
8. Our proposals would build on the existing roles of the Care Quality Commission and Monitor (the Independent Regulator of Foundation Trusts). The overall framework seeks to protect and promote patients' interests in the provision of NHS services by:
  - protecting patient safety
  - ensuring that care is provided to NHS patients on the basis of clinical need
  - securing continuous improvement in quality and efficiency of NHS services
  - providing equitable access to NHS services
  - making best use of limited NHS resources to deliver value for taxpayers' money
  - promoting research and development within the NHS
  - securing high standards of education and training for healthcare professionals

3 Department of Health (2011) The NHS Constitution for England.

4 Propper, C., Burgess, S., Green, K. (2004) Does competition between hospitals improve the quality of care?

Hospital death rates and the NHS internal market. Journal of Public Economics 88, 1247-1272

Gaynor, MorenoSerra and Propper (2010) Death by Market Power; Reform, Competition and Patient Outcomes in the National Health Service

Cooper, Z. N., Gibbons, S., Jones, S. & McGuire, A. (2010). Does hospital competition save lives? Evidence from the NHS patient choice reforms.

Cooper, Gibbons, Jones and McGuire (2010). Does Hospital Competition Improve Efficiency? An Analysis of the Recent Market-Based Reforms to the English NHS

Domberger & Jensen (1997) A review of the international evidence on competitive tendering on central and local government services, Oxford Review, Economic Policy, 13:67-78

DTI (2004) The benefits from competition: Some illustrative cases, Economics paper 9

## Key principles

9. Key *principles* have shaped our proposed approach to sector regulation:
- Primacy of quality
  - Clinical commissioners lead
  - Total transparency
  - Regulation will always play an important role

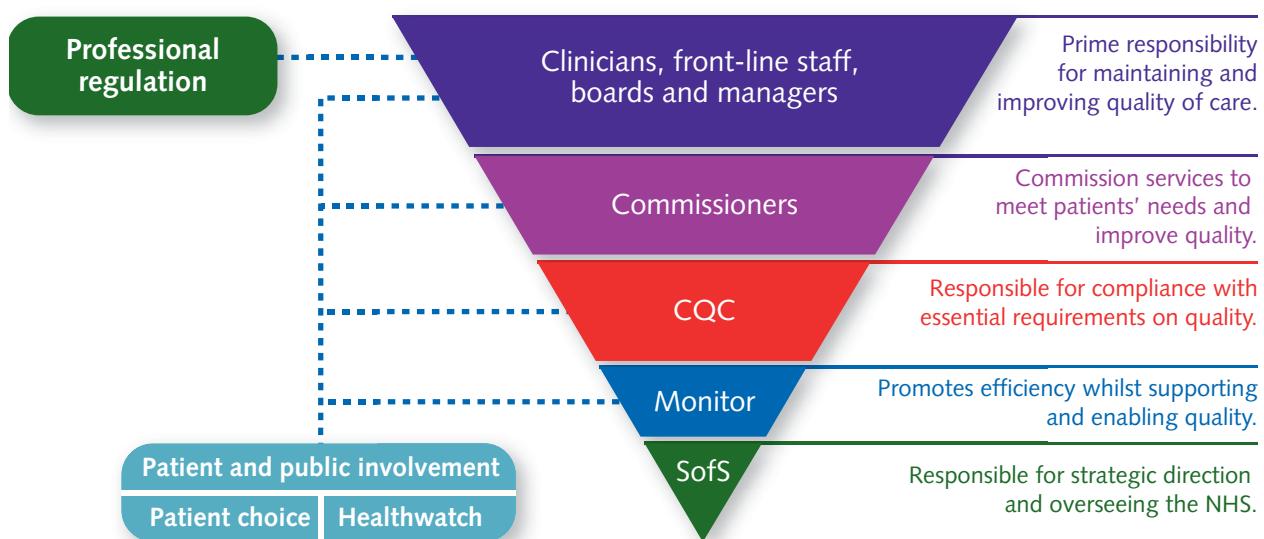
## Primacy of Quality

10. Our measures of success for the NHS will be improvement in quality, outcomes and productivity. However, quality must have primacy as the organising principle for decisions in line with Lord Darzi's vision *High quality care for all*. Lord Darzi set out three dimensions of quality:
- clinical effectiveness
  - safety
  - patient experience.

These will underpin the Outcomes Framework for the reformed NHS.

11. With 'high-quality care for all' as the organising principle, the goal of everyone commissioning, providing or regulating healthcare should be improving quality of care for patients, both now and in the future. This will depend on innovation in the way care is delivered, for example, by providing more integrated services to improve patients' experience of their care and to avoid unnecessary hospital admissions for older people. Clinicians and other frontline staff, managers and the boards of provider organisations, and commissioners will have the greatest influence and, therefore, responsibility for improving quality. The role of regulation is to underpin this by protecting standards and strengthening incentives. For example, by safeguarding essential quality requirements and incentivising adoption of best practice. Figure 2 sets out a 'hierarchy of responsibility for quality'.

**Figure 2: Hierarchy of responsibilities for quality**



CQC = Care Quality Commission  
SofS = Secretary of State

## Clinical commissioners lead

12. A fundamental principle is that clinical experts would take the lead in commissioning NHS services to meet patients' needs and foster improvements in quality and productivity. Commissioners would be expected to keep services under review against ongoing assessments of patients' needs and identify opportunities for innovation and improvement. In particular, it would be for commissioners to decide when and where to use competition, as a tool for driving improvements, informed by evidence as to where competition would be effective, and the benefits of alternative service models. There would be an important role for the NHS Commissioning Board in identifying and disseminating relevant evidence to support clinical commissioning groups in making their decisions and keeping services under review.
13. Our intention is for commissioners to have a full spectrum of options in the procurement of clinical services, working within a framework of rules to ensure transparency and protect patient interests. This framework would be set out in secondary legislation under Part 3 and would be sector-specific. This is necessary to reflect the unique nature of commissioning in the NHS, where there is a mixed economy of providers, and where competition would be effective in some circumstances, but not others. These options would include:
  - Offering patients choice of 'any qualified provider'
  - Offering patients choice from a limited range of providers
  - Competitive tendering
14. Commissioners would be expected to identify opportunities to stimulate innovation and improvement and to give patients more control over their care, using competition and choice where appropriate. Equally, commissioners need to have the option of varying or extending contracts, or awarding new contracts, without going through a competitive tendering process where this would be unnecessarily costly.

*"competition can take many different forms, and sharpening competitive forces is likely in general to be an important tool for most health systems. Policy makers nevertheless need to shape market-type mechanisms with care, to align other policy levers, and to monitor vigilantly, in order to maximise the benefits they secure." (Smith, 2009; page 72)<sup>5</sup>*
15. In addition, there will be circumstances where it would be in patients' and taxpayers' interests to maintain or reconfigure existing services without competition. For example, there are monopolies in the NHS – both at national and local level – where it may be inefficient or unnecessary to introduce competition. Currently, these tend to be acute hospital services that depend on high-cost infrastructure (ie. facilities and equipment) and 24/7 access to highly specialised staff; as well as specialist, tertiary centres.
16. However, the situation will vary in different areas of the country and, over time, with developments in clinical practice and

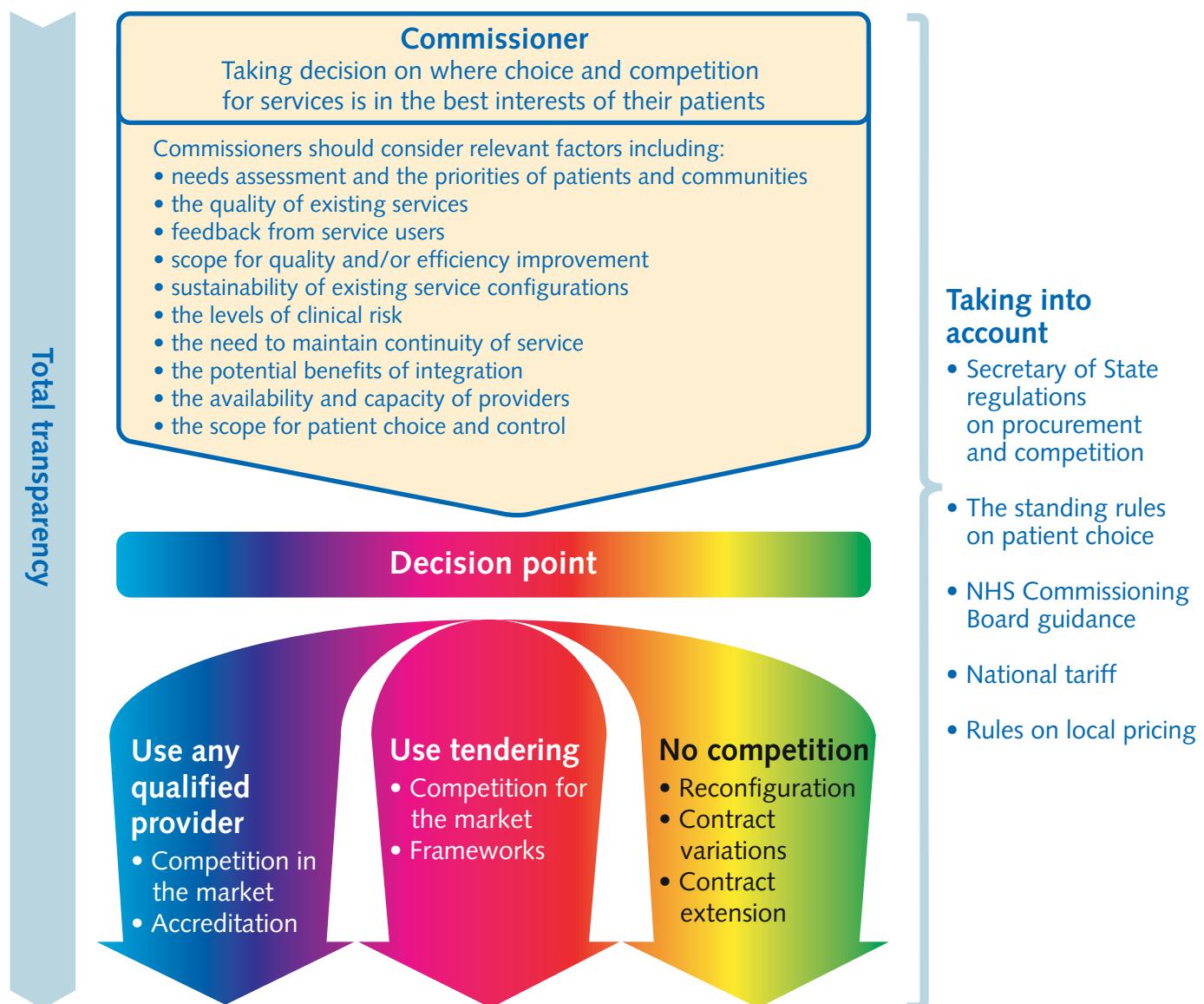
<sup>5</sup> Smith, P. (2009) Market mechanisms and the use of healthcare resources. In Achieving Better Value for Money in Health Care. Paris: OECD. 53–77.

through the development of partnerships across the public, private and voluntary sectors. For example, developments in technologies could enable care to be delivered in ways that are less dependent on hospital infrastructure – as we are already seeing with developments in home dialysis and home chemotherapy.

17. Clinical commissioners will take the lead in these decision because they are

well placed to understand their patients needs. Commissioners will work with local Health and Well-Being Boards to ensure NHS services reflect the needs of the community and are effectively integrated with social care. Our proposals for sector regulation in commissioning aim to protect patients' interests by ensuring transparency in commissioning processes and requiring commissioners to justify their decisions in terms of quality and value.

**Figure 3: Commissioners decide when and how to use competition**



## Total Transparency

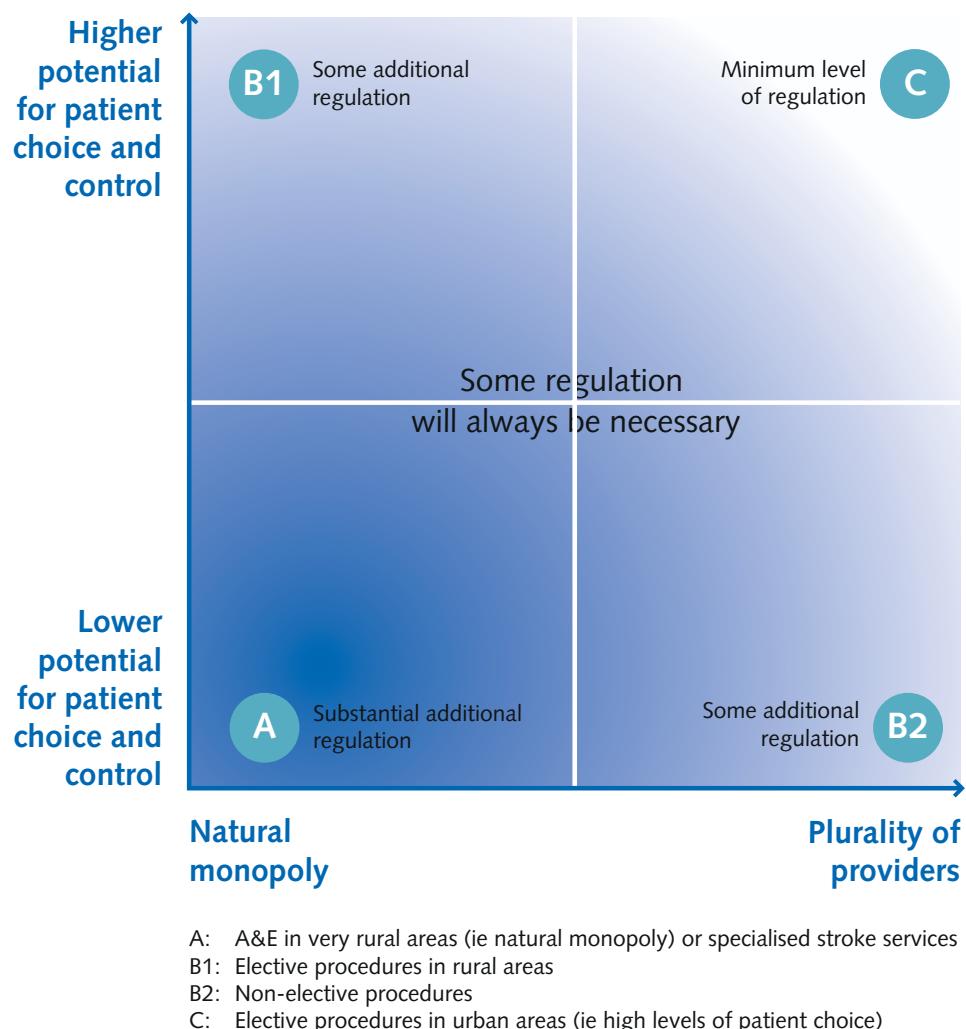
18. Sector regulation would increase transparency in commissioning processes to strengthen public accountability for commissioning decisions and help secure best value. Patients and the public rightly expect transparency with respect to both commissioning and provision of NHS services including:
    - Requirements on quality and access that patients can expect
    - Range of choices available to patients (e.g. of treatment, setting and/or provider);
    - Performance of services, including patient experience and clinical outcomes;
    - Costs of services and the approach to pricing; and,
    - Commissioning processes, including the rationale for decisions on when and how to use competition and on the award of contracts
  19. The previous Government made important progress in these areas. For example, by establishing essential requirements to protect patient safety and by enshrining the defining values and principles of the NHS under an NHS Constitution.
  20. Secondary legislation under Part 3 of the Bill (see Section C) would build on this progress by:
    - increasing transparency in commissioning processes;
    - requiring that commissioners are able to justify their decisions on when and how to use competition (or not) in improving services for patients; and,
- demonstrate that services are being commissioned from the provider(s) best able to meet patients' needs.
- ## Regulation in this sector will always play an important role
21. Sector regulation in healthcare would always play an important role in protecting patients' interests and supporting commissioners to secure value in the provision of NHS services. The proposals set out in Part 3 of the Bill would build on the existing roles of Monitor, as the regulator of Foundation Trusts, and the Care Quality Commission. Whilst rationalising structures by consolidating the current functions of the Cooperation and Competition Panel and some of the functions of Strategic Health Authorities.
  22. **Monitor and the Care Quality Commission would operate a joint licensing regime for providers of NHS services** to ensure essential standards of quality, information and governance. The licence would provide a framework for setting and enforcing of rules and conditions to protect and promote patients' interests.
  23. **The Care Quality Commission would retain its unique responsibility for overseeing compliance with quality requirements** and its independent powers to intervene, where necessary, to protect patient safety.
  24. **Monitor's overarching duty would be to promote economy, efficiency and effectiveness in the provision of services, in the interests of patients.** Monitor's role would complement the role of the Care Quality Commission in protecting

patient safety and support the role of commissioners in securing access to services and improving quality. Building on its existing role as the regulator of Foundation Trusts, Monitor would discharge its duties through the following key functions:

- Licensing providers of NHS services, working with the Care Quality Commission
  - Working with the NHS Commissioning Board to regulate prices for NHS services
  - Enabling integration in the provision of services to patients
  - Protecting patient choice and addressing anti-competitive conduct that acts against patients' interests
  - Working with commissioners to secure continuity of services, where necessary
25. Monitor would need to determine the appropriate level of regulation that it considers necessary and proportionate, in pursuit of its overarching duties, and keep regulatory burdens under review. The appropriate level of regulation will vary in different circumstances. A minimum level of regulation would always be necessary to protect patients' interests, for example, to maintain standards of governance and ensure transparency and the provision of information. Monitor would work with the NHS Commissioning Board to determine how best to regulate prices for NHS services, as a means of strengthening incentives for improvement and to ensure value for money. In addition, Monitor would need to determine where additional regulation is necessary to enable integration, prevent anti-competitive conduct and to secure continuity of services.
26. Additional regulation will be particularly important to protect patients' interests where there is less competition and for services where competition would be ineffective, as shown in Figure 4.

**Figure 4: Regulation and competition will always play an important role**

The appropriate level of regulation will vary in different circumstances.



## What the Bill would *not* do

27. Finally, in setting the context for our proposals on sector regulation, it is important to make clear what the Bill would not do, including:
- No free market
  - No privatisation
  - No price competition

### No free market

28. The Bill would *not* establish a free-market for provision of NHS clinical services where

any provider could potentially deliver any service at the price it thinks the market would be willing to pay. Such an approach would fail to protect patients' and taxpayers' interests because:

- market forces alone would not deliver a comprehensive health service throughout England;
- patients would not be protected from poorer quality or unsafe services; and,
- providers could potentially generate excessive profits, at taxpayers' expense.

## No privatisation

29. Neither do we have any intention to privatise provision of NHS services in the manner of the UK rail, water, gas and electricity sectors; nor to go down the American route where some States rely almost exclusively on the private market for the provision of publicly-funded healthcare. For example, unlike in the rail sector, the Bill would not transform NHS facilities into 'private franchises'.
30. Cases such as Hinchingbrooke Hospital which (based on legislation enacted by the previous government) will be run for a limited period by an independent provider, would be exceptional. Property and staff would remain in the public sector. Our intention is that Hinchingbrooke would be established as a Foundation Trust (or part of a Foundation Trust) in due course.
31. This reflects our commitment to retaining Foundation Trusts as key providers of NHS services, within the public sector, and the Bill would ensure they could not be privatised.
32. In addition, the Bill would prevent a future Secretary of State, Monitor or the NHS Commissioning Board from acting to increase market shares for particular types of provider. This would prevent a repeat of the previous administration's policy of excluding NHS bodies from competing to establish new 'treatment centres' and offering favourable contract terms to private providers.
33. Instead, we will establish a system of regulation which enables patients to access the best possible providers, incentivises improved service quality, and provides a fair 'playing field' for all, regardless of ownership.

## No price competition

34. We have been clear that competition will be based on quality and Monitor and the NHS Commissioning Board would be expected to expand the range of services covered by the national tariff, for example, in community and mental health. And the Bill seeks to reduce incentives for providers to 'cherry pick' simple services by requiring Monitor to take account of variations in the range of services provided by different providers – and variations in the complexity of patients treated – when setting prices.
35. We have strengthened the Bill to ensure that where a national or local tariff is in place, providers and commissioners cannot undercut this. However, the Bill also provides for Monitor and the NHS Commissioning Board to set rules to enable local commissioners to vary the tariff in certain circumstances, for example to enable reimbursement for new, integrated service models. Where applying such flexibilities, commissioners would be expected to evaluate the impact on quality, for example, through appropriate quality metrics. To ensure transparency commissioners would be obliged to maintain and publish a statement detailing how they have applied such flexibilities. Monitor would oversee compliance with the rules and would be able to direct commissioners to implement remedies, where necessary.

36. Where competitive tendering is undertaken for services not covered by the tariff, bids would be evaluated in terms of best value (i.e. awarding contracts to those bidders who provide the best balance of quality and cost, and where appropriate social return, not just the lowest price).

# Section B – Monitor's role and functions

37. In this section, we consider the role of Monitor as the sector regulator for healthcare, its duties and functions and its fit with the broader healthcare system.

## What is sector regulation and why do we need it?

38. Regulation can cover many different areas, but essentially its main aim is to change the way in which providers operate, mitigating for conditions that may negatively affect consumers.

*"Regulation is the act of controlling and conditioning markets and market behaviour. This control can affect the structure, conduct, incentives, performance or rewards in the market"* (Earl-Slater, 1999)<sup>6</sup>

39. Over the years, regulation has played a strong role in the healthcare sector, due to the vital importance of the goods and services it provides. Regulation has helped mitigate against, for example: limited access to services, high prices, perverse incentives and lack of information; as well as ensuring the safety and quality of healthcare services.

40. The Health and Social Care Bill would ensure sector regulation is complete, comprehensive and covers all NHS services. It would also ensure that any undue political influence was removed by

moving economic regulation of healthcare services away from Whitehall control.

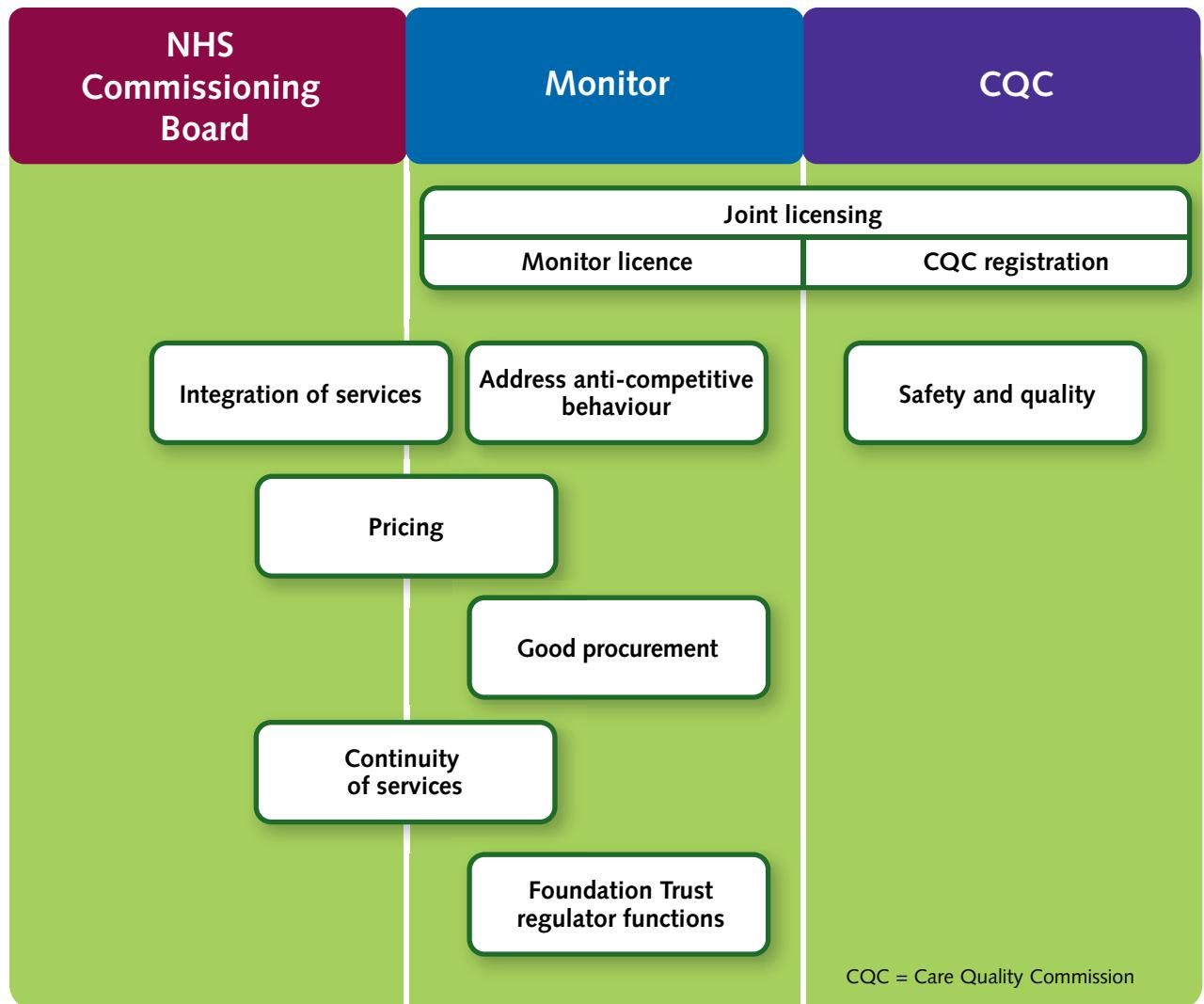
## How will Monitor fit into the system?

41. Monitor's role would be in ensuring that the provision of NHS services operates efficiently and effectively, in the interests of patients. Its responsibilities will interface with the NHS Commissioning Board in terms of service integration, pricing and securing continuity of services. Figure 5 explains the proposed architecture for regulation, as described in Part 3 of the Health and Social Care Bill.<sup>7</sup>
42. Monitor would be accountable to Parliament for discharging its duties and the Secretary of State could intervene if he or she considered that Monitor was significantly failing to perform its functions. This balanced approach is designed to secure the benefits of an independent regulator, while retaining parliamentary oversight.
43. Part 3 of the Bill establishes the statutory framework for sector regulation in the new system. It seeks to create a more comprehensive and coherent framework by rationalising existing structures and building upon the roles of Monitor and the Care Quality Commission (CQC).

6 Earl-Slater, A (1999) Dictionary of Health Economics' Oxon: Radcliffe Medical Press Ltd.

7 This paper focuses on the regulatory role of Monitor and does not consider the full roles and functions of the NHS Commissioning Board or CQC.

**Figure 5: Proposed regulatory architecture**

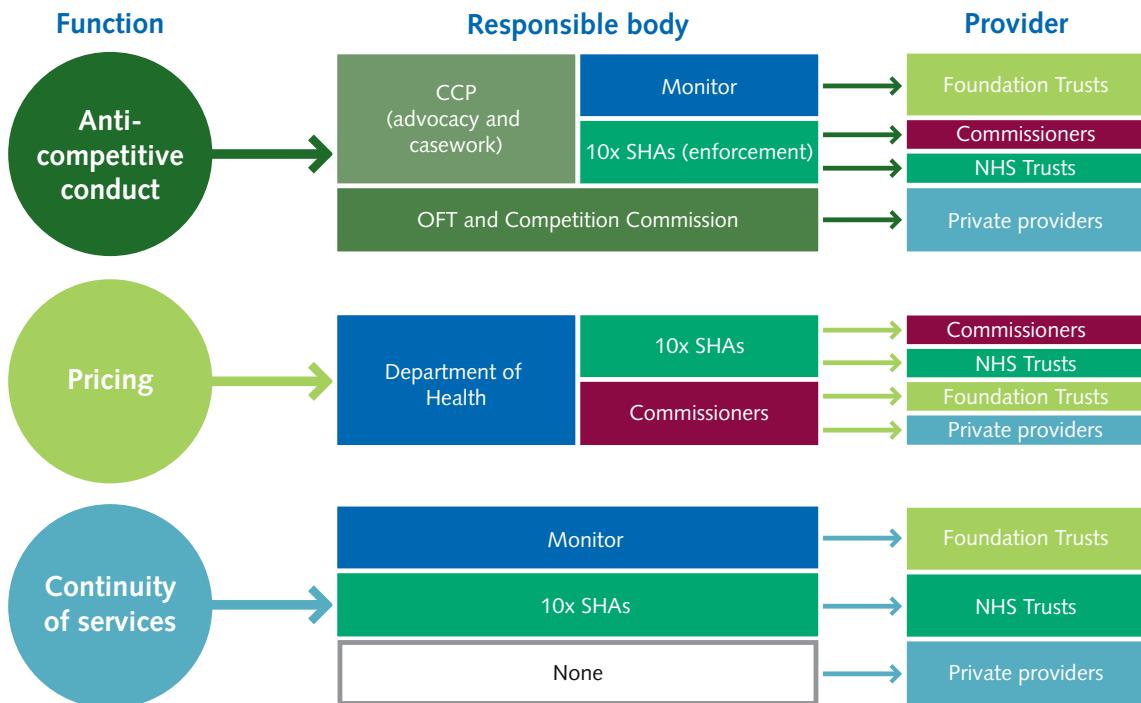


44. Figure 6 shows how currently regulation – to prevent anti-competitive behaviour, regulate prices and measures to support the continuity of services, for each provider type – is carried out by many different bodies. For example, independent sector providers are regulated by Office of Fair-Trading and the Competition Commission (in terms of market behaviours and monopolies),

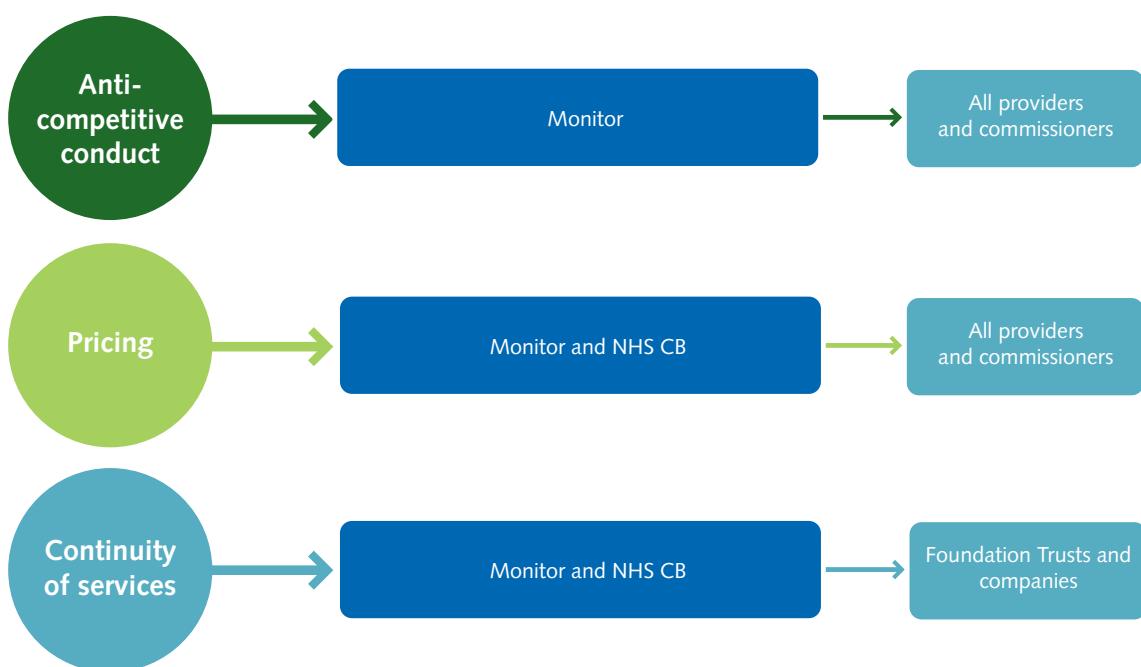
by the Department of Health (in terms of quality standards and policy objectives), and in some cases, there is no regulation in place – e.g there is no intervention or support for the continuity of services of a large independent sector provider. Under the proposed system, regulation will be consolidated and more comprehensive.

## Figure 6: The Bill would consolidate existing regulatory roles under Monitor

The current system is fragmented, duplicative and not comprehensive.



The Bill would consolidate existing regulatory functions under a single, sector regulator.



CCP – Cooperation and Competition Panel  
 NHS CB – NHS Commissioning Board  
 OFT – Office of Fair Trading  
 SHA – Strategic health authority

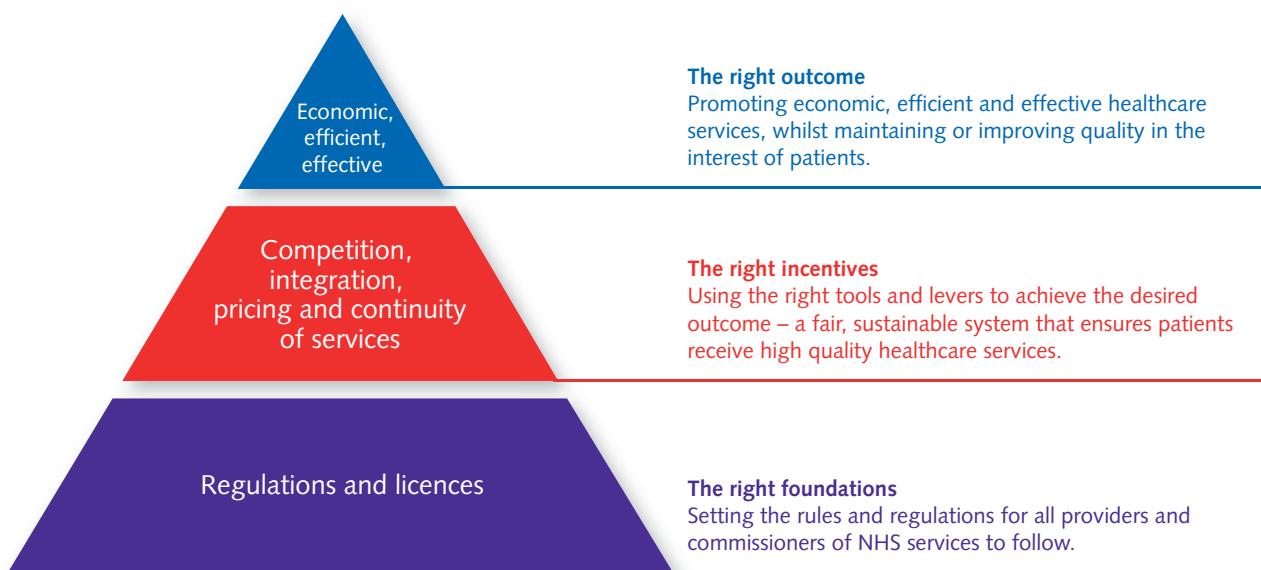
**Monitor – A sector regulator to promote services that are “economic, efficient and effective, and maintains or improves the quality of the services”.**

45. Monitor's regulatory responsibilities will involve general scrutiny of the whole health sector, oversight of pricing, addressing anti-competitive conduct, supporting and enabling integration of services, and a responsibility to ensure the continuity of services where there is a risk of provider failure.
46. Monitor will have a range of tools at its disposal to deliver its regulatory responsibilities. These regulatory tools, such as licensing, pricing and a regime for the continuity of services are described in more detail in the following sections and in the diagram below.

**Licensing: setting and enforcing the rules for providers**

47. Monitor will have powers to operate a licensing regime for providers of NHS services. This will be a key tool by which Monitor will influence and/or change the behaviour of NHS service providers in order to fulfil its duties.
48. A joint licence and registration regime for new providers will operate between Monitor and the Care Quality Commission, as stated in Part 11 of the Bill. Both bodies will work together to minimise duplication.
  - i. Criteria for granting a licence will be published and will operate as the framework within which a decision to license a provider is taken. Where a provider is required to be registered

**Figure 7: The functions of Monitor regulatory tools**



- with the Care Quality Commission, having this registration in place would be a prerequisite for holding a licence;
- ii. Once fully established, the joint licensing and registration process will offer a single integrated application to providers requiring both a licence and registration at the same time.
  - iii. The licence will set out the conditions that the provider of NHS services would have to comply with;
  - iv. Monitor will consult on the first set of standard licence conditions – these and any future licence modifications will be subject to a statutory change control process to ensure transparency and fairness for providers.
  - v. Secondary legislation under Part 3 would enable the Secretary of State to determine exemptions from the requirement to be licensed, to ensure that the licensing regime is proportionate and targeted towards those parts of the healthcare system where it can achieve the greatest benefit.

### **Competition and Integration: the right incentives, working together and in parallel for the benefit of patients**

49. As set out in the Bill, Monitor must exercise its functions with a view to preventing anti-competitive behaviour, where such

behaviour is against the interests of patients, and to enable the integration of healthcare services. These are two distinct, but equally important levers for Monitor to use to ensure that the healthcare sector operates to provide services that are economic, efficient and effective.

50. Patients and the public have consistently told the Government that they want more say and greater choice over their NHS healthcare. For example, a recent survey<sup>8</sup> of 5,000 people revealed that over 80 per cent of patients want more choice over how and where they are treated in the NHS and nearly three quarters of patients want more choice in who provides their hospital care.
- 81 per cent of respondents want more choice in *where* they are treated
  - 79 per cent of respondents want more choice in *how* they are treated
  - 75 per cent of respondents wanted a choice of hospital consultant in charge of their care
  - 75 per cent of respondents wanted a choice over which hospital consultant is in charge of their children's care.
51. Women and older people in particular want to see more patient choice in the NHS. Nine out of 10 people over the age of 55 want to have a greater say in how and where they are treated.

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<sup>8</sup> One Poll carried out the survey using a representative sample of 5,000 people in England. The fieldwork was carried out on 3 and 4 October 2011. The survey was commissioned as part of the Department of Health's ongoing opinion research which seeks to understand people's views and attitudes towards health and NHS issues. This research helps inform Government in its policy-making and is regularly published so that it is available to stakeholders and the general public.

52. There is emerging evidence that competition can, and indeed has delivered benefits to patients and the NHS. These demonstrate that, in some areas, patient choice and competition has lead to better outcomes, increased patient satisfaction and better hospital management.<sup>9</sup>
- "We find that the effect of competition is to save lives without raising costs. Patients discharged from hospitals located in markets where competition was more feasible were less likely to die, had shorter length of stay and were treated at the same cost." (Gaynor et al, 2010).<sup>10</sup>*
- Competition and integration: not mutually exclusive but working together**
- "Competition and integration are complimentary and not contradictory elements of the reforms"<sup>11</sup>*
53. However, feedback from the Future Forum<sup>12</sup> also indicated that patients and healthcare professional want more joined up or integrated services. This, alongside other evidence, shows us that both integration and choice are very important factors in delivering good healthcare services.
54. **More integration.** Integrated care pathways can enable increased collaboration between hospitals and clinicians, between public and independent sector services and between health and social care providers. There is a clear consensus for further integration and more joined-up services and the Bill seeks to encourage and enable the delivery of integrated services. In particular, Monitor has an overarching duty to enable integration where this would improve services or reduce inequalities for patients.
55. **Driven by commissioners.** Clinical Commissioning Groups, supported by the NHS Commissioning Board, should take the lead in promoting integration, as a means of improving services and in enabling patients to have choice and control of their care.

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9 NBER (2010) Death by Market Power: Reform, Competition and Patient Outcomes in the National Health Service. NBER Working Paper No. 16164. Cooper, Gibbons, Jones and McGuire (2010) Does Hospital Competition Save Lives? Evidence from the NHS Patient Choice Reforms.

10 Gaynor, M., Moreno-Serra, R. and Propper, C. (2010) Death by Market Power: Reform, Competition and Patient Outcomes in the National Health Service. NBER Working Paper 16164. Cambridge, MA: National Bureau of Economic Research. Also published as CMPO Working Paper 10/242. Bristol: The Centre for Market and Public Organisation, University of Bristol.

11 Professor C Ham (2011), One of History's great partnerships? Integration Competition, Health Service Journal, 19.

12 As outlined by the NHS Future Forum's current work. [http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/documents/digitalasset/dh\\_127541.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_127541.pdf)

### **Example 1: Competition can enable integration**

Competition within the healthcare sector can enable integration. Tendering is a good example of where commissioners could use competition to drive the development of more integrated care. This process would create opportunities for providers to innovate and ensure that contracts are awarded to the provider(s) best able to meet patients needs.

Research has shown that, for some services with high levels of planned and integrated care, patients often require a coordinated network of providers, "*This does not rule out contestability among providers for roles within that network; nor should it prohibit competition between organisations to be the lead providers within networks for a defined period.*" (Walshe and Ham, 2011)<sup>13</sup>

56. Commissioners will decide which tools are most appropriate – 'one size does not fit all'. For some services and client groups (e.g. older people, end of life care, children with complex needs, the homeless, cancer care), highly integrated services would be likely to best meet patients' and service users' interests. In such cases, commissioners may decide to run a tender for a 'prime contractor' who would be responsible for providing effective care co-ordination and delivery.<sup>14</sup> This is consistent with the Principles and Rules for Cooperation and Competition established by the previous Government, which make clear that:

*"Commissioners must commission services from the providers who are best placed to deliver the needs of their patients and populations.... Commissioners, at board level, should be able to demonstrate a clear rationale for procurement and contracting decisions in terms of quality and value for money"*<sup>15</sup>

57. For other patients and services, commissioners may decide that an effective way of driving-up quality (particularly of some, often neglected, community services) would be to introduce patient choice of Any Qualified Provider, with competition based on quality not on price.<sup>16</sup>

13 Walshe, K. and Ham, C. (2011) Can the government's proposals for NHS reform be made to work? BMJ. 342:bmj.d2038

14 There could be some choice of provider for specific services, e.g. access to diagnostic tests, advice and support, etc – but this would be embedded within a co-ordinated pathway.

15 Principles and Rules for Cooperation and Competition (Principle 1); Department of Health; March 2010.

16 Competition on price alone would not best serve patients' interests because this would introduce perverse incentives for providers to cut costs, possibly at the expense of quality.

## **Example 2: Patient choice works with integration**

Patient choice can work in harmony with integration. For example, there may be some scope to introduce integrated care pathways that give patients more control over their care.

Patients' could choose parts of their care pathway, such as the setting in which they receive that care – for example, choosing to have dialysis or chemotherapy at home or in a clinical setting; or by choosing Any Qualified Provider to deliver key elements of a pathway such as, for example, antenatal education for maternity care. Allowing choice and integration to work together, where appropriate, can create significant patient benefits and improved patient experiences.

58. **Integration enabled by Monitor.** Monitor has a role in enabling the provision of integrated care services. Monitor will have a range of functions at its disposal to achieve this, for example, supporting the NHS Commissioning Board in identifying and spreading good practice in the development of reimbursement systems; and in ensuring that incentives are optimised and aligned. The Bill is very clear that Monitor's core duty means that patients' interests will always come first. Where an integrated service raises competition concerns, and equally where services offering more choice and control raise concerns over integration, Monitor will focus on *what benefits patients*.

## **Addressing anti-competitive behaviour**

59. Part 3 of the Bill seeks to establish appropriate powers for Monitor to ensure that, where there is competition, it operates effectively in the interests of patients and to address anti-competitive conduct that restricts competition against patients' interests. However, it is not the case that every arrangement in the provision of healthcare that had the effect of restricting competition would necessarily be 'anti-competitive'. The test

would be whether such arrangements were acting against patients' interests. For example, in some cases limiting competition by concentrating specialist services in regional centres or in providing services through a clinical network may deliver overriding benefits to patients and would not, therefore, be 'anti-competitive'.

60. The Bill does *not* specifically extend competition into particular services. Determining when and how to use competition as a means for improving quality and value for money will be a matter for commissioners. Neither would the Bill change EU or UK competition law or extend its current application to the NHS.
61. The Bill would empower Monitor to protect patients' rights to choose and address restrictions on competition that were acting against patients' interests as follows:
  - **Statutory powers to set and enforce licence conditions** to prevent conduct that undermined patient choice or restricted competition against patients' interests. The licence conditions would reflect the existing Principles and Rules for

Cooperation and Competition, which were established by the previous Government.

- **Concurrent powers to apply the Competition Act 1998** in the healthcare sector, instead of reserving these matters for the Office of Fair Trading (OFT). Competition law exists to protect the interests of patients (and consumers more generally) against abuses that would harm those interests, not to promote competition as an end in itself or to promote the interests of providers. The Bill would enable competition law to be applied by Monitor: a sector-specific regulator with greater knowledge and expertise of healthcare. This would be particularly relevant for differentiating between where restrictions on competition were acting against patients interests versus where there may be overriding benefits to patients of limiting competition – eg. by concentrating specialist services in regional centres or in providing services through a clinical network.
- **Commissioning regulations on good practice in procurement, patient choice and competition**, overseen by Monitor. This would give the Secretary of State the ability to put the requirements of the existing Principles and Rules for Cooperation and Competition, as they apply to commissioners, on a statutory footing. It would also address the current fragmentation and duplication of functions between the Cooperation and Competition Panel and Strategic

Health Authorities, abolished under the Bill, by consolidating investigative and enforcement responsibilities under a single regulator.

62. **Mergers and acquisitions** involve trade-offs between lessening of competition and potential benefits of improved quality, value and sustainability. However, the potential anti-competitive affects of mergers can impact on a wide range of services and across multiple sectors. The Bill seeks to consolidate oversight of Foundation Trusts mergers within the UK general mergers control regime operated by the Office of Fair Trading (OFT) and Competition Commission. This change will ensure consistency of approach across sectors and eliminate the current risk of double jeopardy for NHS Foundation Trusts. Furthermore, this process aims to improve value for public money, by avoiding duplication of specialist resources between the OFT and Monitor.

**Pricing:** *A tool to create the right incentives in the system.*

63. Pricing is an important lever for strengthening incentives for providers to develop and improve services in line with providers' and commissioners' priorities. The Bill provides that prices for NHS services would be regulated by Monitor with the NHS Commissioning Board.
64. The case for regulating prices for NHS services is strong. Many academics<sup>17</sup> agree that fixed prices will lead to competition

<sup>17</sup> Gaynor et al (2010) "Death by market power: reform, competition and patient outcomes in the National Health Service", covering the period 2003/04 to 2007/08 and published both as an NBER Working Paper and a CMPO (University of Bristol) Working Paper; and Cooper et al (2011) "Does hospital competition save lives? Evidence from the English NHS patient choice reforms", published in The Economic Journal.

on quality, not price, and that by doing so, the standard and quality of healthcare services will increase and that patients' and taxpayers' interests will be protected. For example, evidence from the UK<sup>18</sup> demonstrates that unregulated pricing can result in perverse incentives for providers to cut costs, in order to lower prices at the expense of quality. In addition, evidence from the NHS demonstrates that fixed pricing can reduce transaction costs by reducing the need for price regulation and enabling commissioners to focus on quality – as the Audit Commission recognised:

*"Payment by Results (PbR) has now been largely mainstreamed by the NHS. The change in the financial regime, in particular the increased level of risk to individual organisations, has encouraged both providers and commissioners to strengthen their financial management and information systems, as well as their overall planning, and performance and contract management. Organisations are beginning to use PbR as a tool to identify inefficiencies and redesign care pathways in the interests of patients. This is more evident for provider trusts than for primary care trusts (PCTs)."*

65. Therefore, effective regulation of prices for NHS services should:
- Enable and promote improvements in care for patients and taxpayers;

- Enable efficient providers to earn appropriate reimbursement for their services;
  - Help sustain the NHS offer in the long run (a taxpayer funded health service that is universal and comprehensive based on clinical need, not ability to pay);
  - Not preclude the delivery of the Secretary of State's Mandate for the NHS Commissioning Board;
  - Have regard to the principles of better regulation; and
  - Support movement towards a fairer playing field for providers.
66. To enable this, Part 3 of the Bill would build upon the previous Government's system of Payment by Results, which regulates pricing for NHS services through the national tariff and supplementary guidance. This system will reflect best practice and extend the scope of the tariff where it is in the interests of patients.
67. However, currently, the Department of Health sets the tariff, with limited involvement from commissioners and providers. In other healthcare systems around the world, Governments have delegated price setting to independent organisations, including regulators. Such bodies can create a transparent and stable environment for pricing, outside the influence of politics, so that providers have the confidence to invest, and regulators

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<sup>18</sup> Propper, C., Burgess, S., Green, K., 2004. Does competition between hospitals improve the quality of care? Hospital death rates and the NHS internal market. *Journal of Public Economics* 88, 1247–1272  
Hart, O (1997) "The Proper Scope of Government: Theory and an Application to Prisons" *Quarterly Journal of Economics*, November, 1997.

- can develop strong technical skills in setting prices at efficient levels.
68. Therefore, Part 3 of the Bill would strengthen current arrangements by placing tariff-setting functions on a statutory footing and vesting responsibility in independent statutory bodies. Pricing would be undertaken by the NHS Commissioning Board and Monitor – removing it from political interference.
69. The NHS Commissioning Board would be responsible for specifying services and determining the currencies (i.e. units of services) that would be used as the basis of pricing and payments. The rationale for this is that, commissioners are best placed to specify the currencies they would need in contracting for health services and to ensure this is aligned with priorities for service improvement.
70. Monitor's role would be to develop the pricing methodology and to calculate prices. The rationale is to ensure appropriate independence and objectivity in the pricing process and to ensure that prices reflect a robust understanding of provider costs and structures.
71. At all stages, Monitor and the NHS Commissioning Board will have to agree elements of the tariff with each other. The methodology would be subject to consultation and capable of independent review to ensure transparency and fairness. The prices and rules within the national tariff would be legally binding and independently enforceable.
72. Figure 8 below sets out in more detail the anticipated process and the responsibilities for Monitor and the NHS Commissioning Board for tariff design and setting prices respectively. Monitor and the NHS Commissioning Board will need to work together to agree the detailed functional relationship. Further detail is set out in Annex 1.

**Figure 8: Anticipated high level process for pricing as set out in the Health and Social Care Bill**



## Safeguarding against Cherry Picking

73. Cherry picking occurs where providers undertaking only the more simple interventions for less complex patients are paid an inflated price, based on higher average costs.
74. The tariff should ensure the price paid to providers is accurate and reflective of the services they provide – i.e. prices are adjusted for providers who do not treat the full range of patients, to reduce incentives for cherry picking. So when setting prices Monitor and the Commissioning Board would need to consider, among other factors:
  - i. the impact of variations in the range of services provided by different providers; and
  - ii. the differing needs of the patients treated.
75. If prices accurately reflect the costs of services, providers could openly choose to specialise in a service, for example, only providing abdominal surgery for complex cases – and receive fair reimbursement. Specialisation, for some services can be the preferred option. For example, the Royal College of Surgeons, in regard to children's heart surgery services, believe that "*concentrating surgeons' expertise into specialist centres rather than spreading them too thinly across numerous hospitals will give patients the best quality of care*".<sup>19</sup>

However, it is important that the prices accurately reflect the costs incurred in delivering that service, ensuring correct reimbursement. Therefore, a more precise and reflective pricing system will prevent commissioners over-paying for services and not prejudice providers that specialise in more complex cases.

## Continuity of Services: Ensuring sustainability of services

76. Monitor would have a role in supporting commissioners in securing access to NHS services, to reflect patients' needs.
77. Monitor would achieve this by maintaining an assessment of risk and by proactively intervening in response to distress. Additional licence conditions could be placed on providers for the purposes of securing continuity of services, allowing Monitor to offer assistance and support for the provider to return back to normal operation. Figure 9 illustrates this process.
78. However, if a provider of NHS services does become unsustainable, there must be a legal framework that provides effective safeguards to protect patients' and taxpayers' interests. The Health and Social Care Bill sets out a clear framework to secure continued access to NHS services,<sup>20</sup> that:
  - **Protects patients' interests:** Patients must be able to access high quality services to meet their needs and those services must

19 <http://www.receng.ac.uk/media/medianews/rcs-statement-college-responds-to-the-royal-brompton-judicial-review-decision>

20 The continuity of service regime is covered in part 3 of the bill under Clauses 96 and 97 (under licensing) and under clauses 122 and 123 (under pricing). Chapter 5 (health administrations) and chapter 6 (Financial assistance), in part 3 also set out where the continuity of service regime would apply. In addition, clauses 171 to 175 in part 4 of the Bill refer to the continuity of service regime in respects of Foundation Trusts.

continue to meet the quality requirements monitored by the Care Quality Commission;

- **Is an evolutionary approach:** The existing “unsustainable provider” regime, for foundation trusts, as set out in the bill, would be maintained and significantly improved. The framework would also extend equivalent protection to NHS services provided by a company, through a health special administration regime;
- **Ensures commissioners take the lead:** clinical commissioning groups (CCGs) would take the lead in securing continued access to NHS services, overseen by the NHS Commissioning Board;
- **Ensures proactive action is taken:** Monitor would support commissioners to secure continued access to NHS services through proactive intervention to prevent failure. Monitor would be able to intervene based on an ongoing assessment of risk to the provision of NHS services. Interventions would be enabled by Monitor’s licensing regime and would include:
  - the ability to access a provider’s records and premises
  - requiring a provider to produce a turnaround plan to reduce the risk to continuity of NHS services
  - requiring a provider to appoint turnaround experts to increase board capacity to resolve the issues facing the organisation.

- **Makes the clinical case for change:** If services become unsustainable in their current form, proposed solutions would be driven by the clinical case for change – agreed by CCGs and developed through consultation with the broader clinical community, the local Health and Wellbeing Boards, Local HealthWatch and the public; and,
- **Ensures decisions are taken locally and democratic accountability is maintained:** Local authorities would have scrutiny of all service changes in failure.

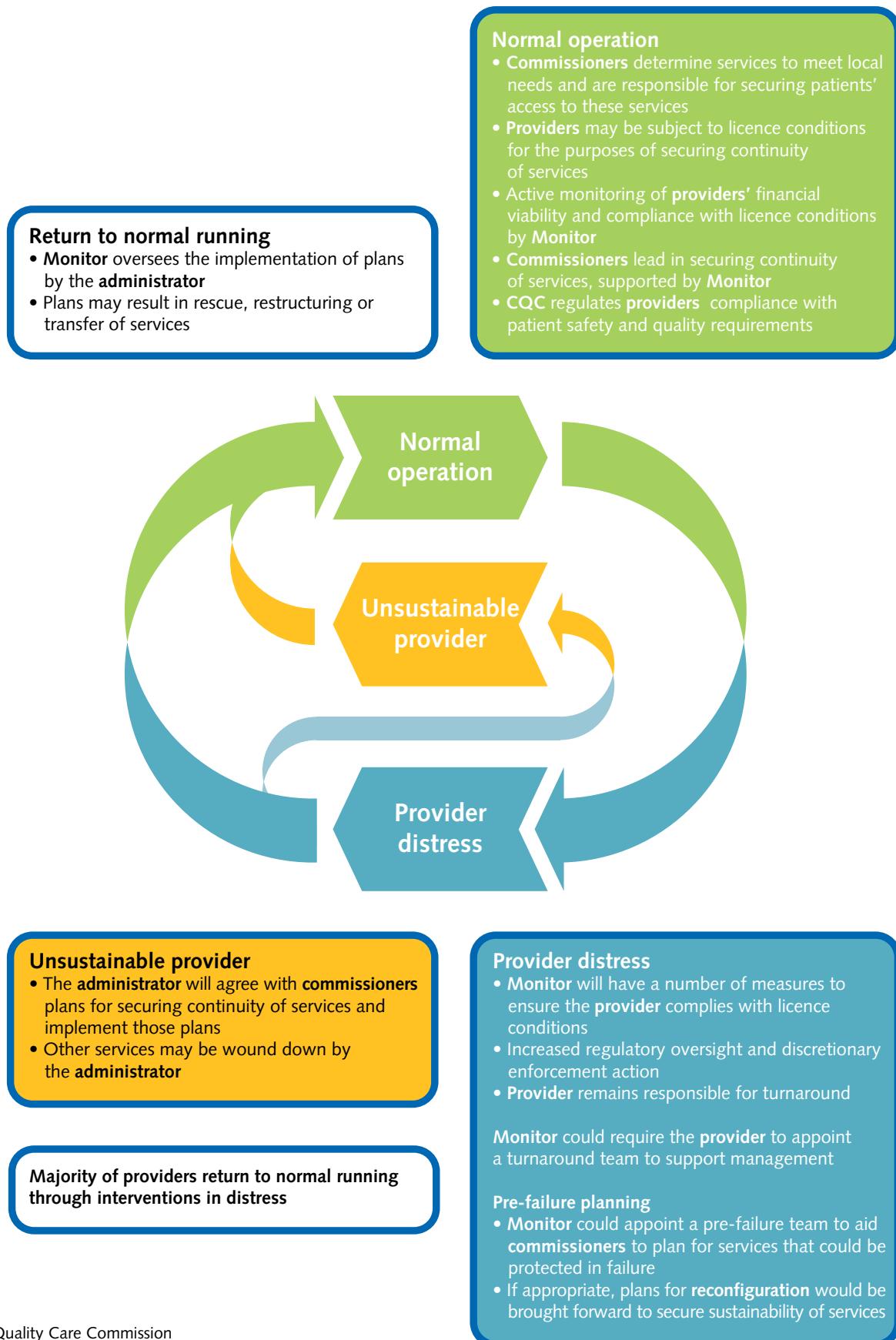
79. More details on the Government’s proposals can be found in the document *Securing continued access to NHS services*.<sup>21</sup>

## Conflicts between functions

80. The Bill would require Monitor to make arrangements within its organisation to ensure that there was no conflict in decisions relating to its functions as the regulator of Foundation Trusts and its broader functions as sector regulator. In addition, where Monitor considered that a conflict had arisen in the exercise of its functions, the Bill would require Monitor to resolve such conflict in the manner it considered best. As part of its annual report, Monitor would be required to publish a statement setting out its arrangements for managing potential conflicts of interest and a summary of its decisions on resolution of any individual conflicts that had arisen during the year.

21 [http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/documents/digitalasset/dh\\_129819.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_129819.pdf)

**Figure 9: NHS Continuity of Services Regime – Health and Social Care Bill 2011**



## **Conclusion**

81. Regulation within the healthcare sector has always been present albeit partial and fragmented. Establishing Monitor as a strong independent sector regulator will provide a comprehensive, but simplified regulatory system, incorporating all providers of NHS services.
82. Monitor's overriding statutory duty would be to protect and promote patients' interests, ensuring that NHS services are economic, effective and efficient. Using the right incentive and the right tools, Monitor will ensure that anti-competitive behaviour is addressed and that integration and choice are enabled where appropriate. This will be achieved, for example, by regulating prices through the national tariff and by ensuring there is a proper regime in place to address problems where a provider gets into financial difficulty.

# Section C – Secondary Legislation: Putting the Policy into Practice

## Introduction

83. Section A of this briefing document set out the aims and principles behind our plans for reform of the healthcare landscape. Comprehensive sector regulation is one of the cornerstones of that vision. Section B set out how Part 3 of the Bill

will establish the legislative framework for sector regulation, developing Monitor's functions, building on its existing role as the regulator of Foundation Trusts. This section looks in more detail at our policy intentions for key secondary legislation under Part 3.

**Table 1 – Proposals to enact Regulations under Part 3 of the Bill**

Function	Clause	Parliamentary Procedure	Description	By when?
Licensing	Clause 80	Negative resolution	<b>Definitions</b> – identifying the 'service provider' that would be subject to the statutory requirement to hold a licence.	April 2013
	Clause 82	Affirmative resolution	<b>Exemptions</b> – determining exemptions from the requirement to hold a licence	April 2013
	Clause 83	Negative resolution	<b>Exemptions</b> – mechanisms for revoking or withdrawing exemptions.	April 2013
	Clause 98	Affirmative resolution	<b>Licence modifications</b> – objection percentage and share of supply threshold for referring disputed licence modifications to the Competition Commission	April 2013
	Clause 103	Affirmative resolution	<b>Definitions</b> – calculation of turnover	April 2013
Pricing	Clause 118	Affirmative resolution	<b>Pricing methodology</b> – objection percentages and share of supply threshold for referring disputes over the pricing methodology to the Competition Commission.	April 2013

Function	Clause	Parliamentary Procedure	Description	By when?
Commissioning	Clause 71–73	Negative resolution	<b>Commissioning regulations</b> – requirements as to procurement, patient choice and competition and associated investigative and enforcement powers.	April 2013
Continuity of Services (General)	Clause 135	Negative Resolution	<b>Risk pool (financing to secure continuity of services)</b> – commissioner charges	April 2013
	Clause 139	Affirmative Resolution	<b>Risk pool (financing to secure continuity of services)</b> methodology for provider levies – objection percentage and the share of supply threshold for references to the Competition Commission.	April 2013
Continuity of Services (Independent Sector)	Clause 127–129	Affirmative resolution	<b>Health Special Administration</b> – to make further provisions about health administration orders	April 2014
	Clause 127(9)	Negative Resolution	<b>Health Special Administration</b> – insolvency rules, subject to approval from Insolvency Rules Committee	April 2014

84. Subject to Royal Assent of the Bill, we will publish detailed proposals for consultation, during Summer 2012, on the regulations we consider would be necessary to underpin implementation of Part 3 (as shown in Table 1). Peers wishing to examine the full range of potential secondary legislation under Part 3 of the Bill will be able to do so by reference to the Delegated Powers Memorandum, published when the Bill entered the House of Lords.<sup>22</sup>

## Licensing

85. Chapter 3 of Part 3 introduces licensing of NHS services providers. Licensing will be

the backbone of Monitor's role as a sector regulator. By applying standard and/or special conditions to licences, Monitor will be able to use the licensing regime to support commissioners to ensure continuity of essential services, to promote patient choice and tackle anti-competitive behaviour, to ensure compliance with the pricing regime, and to prevent "cherry picking".

86. The key elements of the licensing framework are set out in the Bill, including mandatory provisions such as the requirement that all licences contain a standard condition on transparency (clause 101), and provisions giving Monitor

<sup>22</sup> Health & Social Care Bill 2011 – Memorandum for the House of Lords Delegated Powers and Regulatory Reform Committee (Updated to reflect the Bill as introduced in the House of Lords), Dept of Health, 13 September 2011. (Discussion of Part 3 begins at paragraph 588).

explicit powers to set licence conditions relating to continuity of services (clause 97). However, there are other elements that it would not be appropriate or helpful to include on the face of the Bill. The delegated powers in clauses 80, 82 and 83 deal with some of these.

87. In parallel with Parliament's consideration of the Bill, Monitor has published initial proposals for the licensing framework,<sup>23</sup> including draft licence conditions, based on Part 3 as it was introduced into the House of Lords. This will support early engagement with stakeholders and inform Parliament's discussions. It will also inform the Department of Health's work in developing regulations to support the licensing regime, particularly in undertaking analysis to determine the case for any exemptions from the statutory requirement to hold a licence.

#### **Scope of the requirement for healthcare providers to hold a licence**

88. These regulation-making powers deal broadly with which providers of NHS services would and would not be subject to the requirement to hold a licence. The default position would be that all such providers would need a licence unless they fell within the provisions of regulations made under clause 80 or 82. The regulation and direction-making powers in clause 83 allow exemptions granted through regulations to be revoked in either individual cases or where an exemption has been granted to a particular type or group of providers.

#### **Definitions – identifying the service provider required to hold a licence**

89. We are committed to keeping regulatory burdens to a minimum and, where regulation is necessary, to ensuring that it is reasonable and proportionate. The definitional powers under clause 80(2) would work to this end by identifying the service provider that would be subject to the statutory requirement to hold a licence. Regulations under this clause would deal with situations where two or more persons are involved in different capacities in providing a particular service.
90. For example, a GP practice may enter into arrangements with the local Foundation Trust for one of its consultants to provide a minor surgery service for its patients on the practice's premises. There are three persons or bodies involved, in different capacities, in providing the service. The GP practice provides the premises, equipment and so on, the Foundation Trust provides specialist staff (eg. consultants; specialist nurses), and these individuals use their skills, experience and time to carry out the various procedures for the practice's patients. If a licence is required for that particular service, it may not necessarily be reasonable or proportionate to suggest that the GP practice, the Foundation Trust and the individual practitioners should each be required to hold one.
91. Definitional regulations under clause 80(2) would be used to identify which person(s) would be the "service provider" in such cases, and therefore responsible for obtaining a licence, if one is required. The regulations will take a pragmatic approach,

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<sup>23</sup> Developing the new NHS Provide Licence: A Framework Document Monitor, 15 November 2011

seeking to keep the arrangements as simple and non-bureaucratic as possible. It is likely that 'the provider' will, in most cases, need to be the 'main contractor' as defined in the contract.

## Exemptions

92. The delegated powers under clause 82 are also in line with our overarching aim to ensure that sector regulation is reasonable and proportionate. These allow for a system of exemptions as an essential element of the licensing regime.
93. The starting point for considering potential exemptions is the scope of existing statutory requirements for providers to be registered with the Care Quality Commission. Clause 81 makes clear that a licence holder who is providing NHS services that carry a requirement to be registered with the Care Quality Commission, but who is not so registered will automatically be deemed to be in breach of the requirement to hold a licence. Thus CQC registration, where it is required, is a fundamental cornerstone of the licensing regime.
94. However, there are a small number of health care providers who are not currently required to be registered with the Care Quality Commission, for a variety of reasons.<sup>24</sup> As part of our work on developing the exemptions proposals we are considering whether or not these providers should also automatically be exempt from licensing requirements. Conversely, it is also possible that there will be a (probably small) number of providers offering clinically high risk but low volume services who will require registration with CQC, but may be exempted from the requirement to hold a licence.
95. The policy as to how any exemptions would operate is still in development, but it is likely that matters such as size of provider, the nature of the services to be provided, the impact on the local healthcare landscape, and overarching cost/benefit considerations, may all be relevant factors in deciding whether a particular provider should be licensed.
96. For example, as the Explanatory Notes to the Bill suggest,<sup>25</sup> a small GP practice providing a traditional "gatekeeper" service may not need to be licensed, if it is in an area with a good supply of GP services so that the practice's impact on that area is relatively small. It seems possible that in such a case the costs of obtaining a licence (to both the GP practice and Monitor) would outweigh the benefits. On the other hand, a larger GP practice providing a range of additional services and/or covering a remote area with limited or no alternative provision would have a much greater impact on the area it serves. The benefits of requiring it to hold a licence, which would allow Monitor to pick up on any potential problems at an early stage and offer support to protect continuity of services, may well outweigh the costs. But it is

<sup>24</sup> At the time of writing, these are General Practitioners (but this group will be subject to CQC registration from April 2013); Physiotherapists; Occupational Therapists; Clinical Psychologists; Speech and Language Therapists; Cognitive Behaviour Therapy Practitioners, and Psychotherapists/Counsellors.

<sup>25</sup> Health and Social Care Bill, Explanatory Notes, page 120, paragraph 717(HL Bill 92 EN, published 12 September 2011).

important to emphasise that these are only hypothetical examples for illustrative purposes at this stage.

97. Regulations under clause 83 may also make provision for exemptions to be revoked, either because the provider has requested it or because the Secretary of State considers it to be inappropriate for the exemption to continue. As with the clause 82 regulations, the scope is broad, allowing revocation of parts of an exemption, or in respect of a particular provider, as well as of an exemption as a whole. There may be a number of reasons why an exemption would need to be revoked. For example, a provider who decides to expand the range or type of services it provides may no longer meet the terms of the exemptions regulations, or the introduction of a national pricing tariff that applies to services offered by a previously exempted provider type may necessitate the introduction of a licence requirement for those providers.
98. Subject to Royal Assent of the Bill, we will publish details of our proposals for any exemptions from the requirement to hold a licence, for consultation, in Summer 2012. This will set out the Government's rationale for any exemptions, taking into account the factors mentioned in the preceding paragraph, but also carrying out a thorough risk analysis to determine where licensing will provide a sensible and proportionate regulatory response to the risks identified. We will also, of course, take into account Monitor's emerging methodologies for both licensing criteria and conditions.

99. Taken together, these regulation-making powers will serve to set the scope of Monitor's licensing regime, allowing it to form the foundation from which Monitor can exercise its other regulatory functions. We will publish our policy proposals for these regulations for consultation in Summer 2012.

## Pricing

100. Chapter 4 of Part 3 makes provisions in respect of Monitor's duty, working in conjunction with the NHS Commissioning Board, to develop the national tariff for NHS health care services. In the new regulatory system the NHS Commissioning Board and Monitor will collaborate to set prices. This will ensure fair price setting, without political interference. Monitor would publish the national tariff document, which would show the range of services to which the tariff would apply; the methodology used to determine prices; the national prices themselves; and guidance on implementation.
101. Monitor would consult on the draft national tariff document, and consultees would be able to object to the pricing methodology being proposed. Clause 118 provides that if the number of objections met certain thresholds, Monitor could make a reference to the Competition Commission who would review Monitor's proposal – and the objections received – against Monitor's duties and may determine that changes are needed to protect patients' interests.<sup>26</sup> Those thresholds would be set out in

<sup>26</sup> The alternative is that Monitor reconsiders the proposed methodology itself and reissues, although this could result in a further cycle of objections and potential reference to the Competition Commission.

- regulations, allowing a route by which the pricing methodology can be referred to an independent body for independent scrutiny.
102. This mechanism furthers the regulatory regime as it ensures that prices are transparent and fair. Consulting on all elements of the national tariff before it is finalised offers providers and commissioners a chance to see how prices are set and what they will be. The opportunity to object to the methodology and have it referred to the Competition Commission ensures that Monitor's proposals are consistent with its overarching duties to protect and promote patients' interests.
103. The Competition Commission will not be setting the prices, only making adjudication on the methodology. They will not base any decision to agree the methodology on competition grounds. Its role would be to adjudicate as to whether the proposed methodology was consistent with Monitor's duties.
104. The regulations will outline two or three percentages. There will be two simple proportion percentages for providers and commissioners and this will be the threshold for a reference to the Competition Commission. For example, the regulations may state if less than 20% of providers (or commissioners) object to the pricing methodology, it can be finalised by Monitor without reference to the Competition Commission.
105. The provisions also allow the Secretary of State to state a share of supply threshold for providers. If this is used, the regulations will state the threshold for this calculation and what is meant by the share of supply. For example if providers totalling 20% or greater of the providers of a particular procedure object to the methodology for setting the price for that procedure, the methodology could not be finalised unless a reference was made.
106. We will publish our proposals for these regulations for consultation in Summer 2012.

## Commissioning

107. Through clauses 71-73 the Secretary of State can make regulations on Clinical Commissioning Groups and the NHS Commissioning Board to: ensure that commissioners adhere to good procurement practice; to protect patient choice and, to prevent anti-competitive behaviours by commissioners that are not in the patients' interest. In particular the regulations may make provision to prevent conflicts of interests (eg GPs as commissioners and providers). The broad purpose of the regulations is to ensure commissioning represents fairness, transparency, efficiency and value for money, where patients' needs and interests come first.

108. Specifically clause 71 sets out that the NHS Commissioning Board and Clinical Commissioning Groups will be subject to regulations. We envisage that the regulations will cover:
- **good procurement practice**, particularly in respect of competitive tendering, such as advertising contracts, ensuring fair specifications, applying consistent and fair evaluation criteria, addressing conflicts of interest and transparency in decisions to terminate or extend contracts;
  - **patient choice**, including advertising for providers to be included in the set of providers from amongst which patients can choose (the "choice offer"), ensuring fair specifications, ensuring patients are aware of the choices on offer;
  - **preventing anti-competitive behaviour** such as preventing commissioners colluding with providers against patients' interests, for example through choosing a procurement route that favoured certain providers and prevented equally capable providers from offering their services;
  - **requirements relating to the management of potential conflicts** between the interests involved in commissioning services and the interests involved in providing services.
109. Clause 72 gives Monitor the power to investigate suspected breaches of these regulations and take enforcement action as required (such actions being limited to ordering the infringing party to comply with the regulations or, in an extreme case, declaring a contract void if it has been entered into in breach of the regulations). The regulations would set out conditions under which Monitor could accept undertakings, instead of pursuing enforcement action, to remedy the breach of the regulatory requirements.
110. The Bill contains detailed provision about what requirements the regulations may impose and the powers Monitor has associated with those requirements. The power to impose those requirements has been proposed in secondary legislation rather than on the face of the Bill so that the regulations can be updated to reflect:
- any developments in general procurement law (including case law);
  - developments in best practice in procurement of healthcare services.
111. Our policy intention is that these regulations will clarify that commissioners will have a spectrum of procurement options when commissioning services, within a framework of rules to ensure transparency, due process and a clear rationale for decisions.
112. Empowering commissioners to be able to choose from a range of procurement options for when and how to use competition is important for ensuring sustainable, comprehensive provision of NHS services because they can affect both clinical and financial viability. For example, commissioners may decide to centralise specialist services in regional centres where evidence demonstrates this would improve health outcomes. Commissioners may also decide to bundle services together that would utilise similar fixed assets and staff (eg. elective orthopaedics and trauma surgery) in order to deliver value for taxpayers' money and prevent

cherry picking. Bundling the right services should also enable more integrated services. Importantly, the Bill would *not* force commissioners to fragment services through tendering models simply to increase competition.

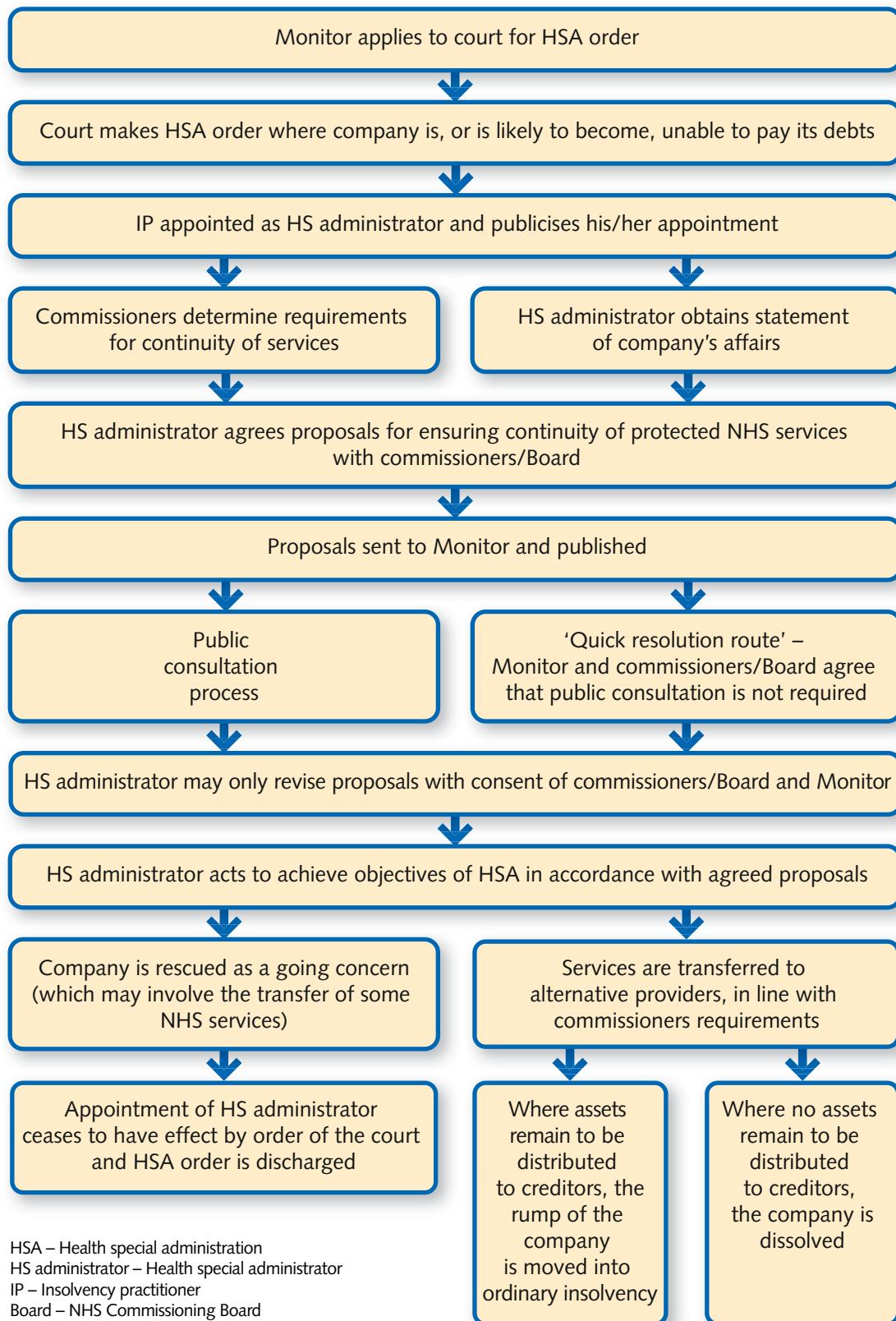
113. These are complex decisions and we intend, through the Bill, to require that commissioners are able to demonstrate the rationale for their decisions in terms of quality and value for patients. For example, commissioners would need to articulate a sound rationale on the quality and value for money benefits to patients of limiting tenders to incumbent NHS suppliers or the decision to move centralised services to a model of competition for the market. There will also be a role for Monitor in investigating potential breaches of the regulations and to direct appropriate remedies, where necessary.
114. We have already laid out in Section A how clause 71 will support Commissioners. In this way the regulations would place the relevant elements of the existing Principles and Rules for Cooperation and Competition (PRCC) on a firmer statutory footing. Where possible we also intend to provide as much flexibility as possible to Commissioners to commission services in ways which are in the best interests of patients.

115. These regulations will be complemented by guidance from the NHS Commissioning Board which will cover good practice in commissioning and will be linked to the priorities set out in the Secretary of State's "mandate" for the NHS Commissioning Board. The regulations also complement the "standing rules" which will set out the legal basis for the right in the NHS Constitution for patients to make choices about their NHS care and to information to support these choices.
116. What these regulations will not do is to place patient choice and competition above patients benefitting from convenient safe and efficient care pathways, which most effectively meet their needs.
117. The policy and draft regulations will be published for consultation during the Summer of 2012.

## **Continuity of Services: Health special administration procedure for corporate providers of NHS services**

118. Parts 3 and 4 of the Bill provide a transparent framework for addressing unsustainable providers of NHS services focused on securing patients' access to essential services and avoiding "bail outs" for inefficient services at the taxpayers' expense.
119. Part 4 (clauses 170 to 175) updates and improves the existing arrangements for NHS foundation trusts under the Health Act 2009 (the 'unsustainable provider' regime).
120. Since those mechanisms would be inappropriate to deal with the failure of a corporate provider of NHS services, Chapter 5 of Part 3 (clauses 125 to 130) introduces a new and distinct health special administration procedure for companies.
121. To protect the interests of patients and those with a financial interest in a failed entity, Chapter 6 of Part 3 (Clauses 131 to 143) establishes financial assistance mechanisms to fund the continuity of NHS services, in line with Commissioners' requirements. Those mechanisms would apply to both the 'unsustainable provider' regime for foundation trusts and the health special administration procedure for companies.
122. The following considers only the health special administration procedure set out in Chapter 5 of Part 3.
123. The health special administration procedure could only be applied in the event of the failure of a company providing NHS services which is subject to 'continuity of services' licensing obligations. The process would provide an alternative to general corporate insolvency procedures and would provide a last resort option where prior regulatory interventions have either been exhausted or are not considered appropriate in the circumstances of a particular failure to protect the interests of patients.
124. Powers are taken in the Bill to set out the detail of the health special administration procedure in secondary legislation. While those regulations will be subject to consultation and Parliamentary approval (using the affirmative procedure) the following diagram gives an illustrative example of how the process might operate.

**Figure 10: Illustrative process of Health Special Administration**



125. The health special administration procedure will be based on existing corporate insolvency law – principally the Insolvency Act 1986. Special administration regimes, for example those in the energy transmission,<sup>27</sup> postal services<sup>28</sup> and investment bank<sup>29</sup> sectors, provide useful precedents. Clause 127 therefore sets out that the regulations may apply (with or without modifications) the provisions of the administration process set out in Part 2 of the Insolvency Act 1986 and related provisions, and also other legislation relating to the law of administration and insolvency.
126. Of course, healthcare provision is unique and through the development of the regulations in consultation with interested parties, it will be possible to ensure that the regime meets the particular needs of the healthcare sector. This will be achieved by modifying the application of insolvency law, where necessary, to ensure that the regime is fit for purpose.
127. To ensure legitimacy and transparency, health special administration will be a court-based regime and clause 125 therefore provides that a health special administration order may only be made by the Court on the application of Monitor.
128. The objective of health special administration (clause 126) is to ensure the continuity of NHS services that commissioners determine are essential. There will not be any upfront designation of those NHS services that would be protected in failure. Instead the health special administrator would work with commissioners to determine which NHS services would be secured, and how that should be achieved case by case. The regulations will set out further details around this process.
129. The objective would ultimately be achieved by rescuing the failed provider as a going concern and/or transferring those services to alternative providers. The emphasis would be on rescue and transfers would only be permitted in limited circumstances, for example where transfers are necessary to ensure sustainability of services going forward. That approach is consistent with existing special administration regimes and the regulations will set out detailed transfer scheme arrangements.
130. Clause 127(4) provides that the regulations can make provision around the commencement of standard insolvency procedures and the enforcement of security. This will enable the regulations to detail circumstances in which Monitor may intervene in the event of failure, where necessary to ensure service continuity, and seek a health special administration order from the court. That approach would again be consistent with special administration regimes in other regulated sectors.
131. Where a health special administration order is made in relation to a corporate provider, a qualified insolvency practitioner would be appointed as the health special administrator and would take control of the failed company. The health special administrator would be an officer of the

27 Energy Act 2004

28 Postal Services Act 2011

29 Investment Bank Special Administration Regulations 2011

court and their principal duty would be to ensure the achievement of the continuity objective set out in Clause 126. The regulations may include requirements for the health special administrator to consult on actions that he intends to take to ensure service continuity – the detail of that process will form an important part of the consultation on the draft regulations.

132. Due to the complexities of insolvency law, the particular requirements of the healthcare sector and the extensive consultation requirements set out in the Bill, the health special administration regime would not come into effect before April 2014. A public consultation on the draft Regulations is expected to commence in 2012.

## **Financial Assistance in Special Administration Cases**

133. Chapter 6 of Part 3 provides for a duty on Monitor to establish financing mechanisms to enable trust special administrators appointed to foundation trusts and health special administrators appointed to companies to secure continued access to NHS services.<sup>30</sup> In particular, Monitor would be able to establish and maintain a fund for the purposes of complying with that duty. The provisions allow Monitor to fund the mechanisms via a provider levy, which would be calculated via a methodology that Monitor would be required to develop, consult and publish.

134. Clause 135 makes provision for the Secretary of State to make regulations giving power to Monitor to require commissioners to contribute to these financial mechanisms. As well as dealing with the practicality of establishing these mechanisms, the policy intention is to strengthen incentives on commissioners to address risks to service continuity and to proactively identify potential alternative providers wherever possible.
135. The scope and content of the regulations are still being developed. However, it is likely that the regulations would have the following features:
- a requirement on Monitor to develop a methodology for commissioner charges;
  - a requirement on Monitor to consult on the methodology before it can impose the methodology;
  - a requirement on Monitor to calculate the amount each commissioner is to pay under the charges and when the charge will become payable for each financial year;
  - a requirement on Monitor to recalculate the charge, where a commissioner reasonably believes that it has been miscalculated;
  - an ability for Monitor to recover unpaid charges.
136. Clause 136 provides for Monitor to impose a levy on providers, and clause 138 requires Monitor to consult on its proposals to exercise its powers under clause 136. Providers would be able to object to Monitor's proposals. Clause 139 provides that if the number

<sup>30</sup> More details on the Government's proposals can be found in the document *Securing continued access to NHS services*: [http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/documents/digitalasset/dh\\_129819.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_129819.pdf)

of objections met certain thresholds Monitor's proposals would have to be referred to the Competition Commission, who would independently judge whether the levy proposed was appropriate and in line with Monitor's overarching duties to protect and promote patients' interests. Those thresholds would be set in regulations, allowing a route by which Monitor's proposals can be referred to an independent body for independent scrutiny.

137. The objection threshold regulations for provider levies will ensure these are transparent and fair. The regulations would allow an independent assessment of the levy methodology, should an objection threshold be met following a consultation. Consulting on the levy methodology before it is finalised will allow providers a chance to see how provider levies will be set. This creates a more stable environment encouraging better long term planning.

138. We envisage that the objection percentage would be expressed as a percentage of all relevant licence holders. Where the thresholds are met and Monitor's methodology is referred for independent scrutiny by the Competition Commission it would be considered on the following specified areas:

- whether Monitor has given sufficient regard to its duties in producing the methodology; and if not
- whether Monitor's failure to do so might operate against the public interest; and
- whether remedies could be made to address the identified effects against the public interest.

139. There will be a public consultation on these proposals in Summer 2012.

# Annex 1

**Table 2 – Pricing: Anticipated division of responsibility between Monitor and the NHS Commissioning Board**

Please note Monitor and the NHS Commissioning Board would need to work together to agree the detailed functional relationship. The rationale box explains why these different elements of the national tariff are required and if necessary why a particular organisation has the lead for that element.

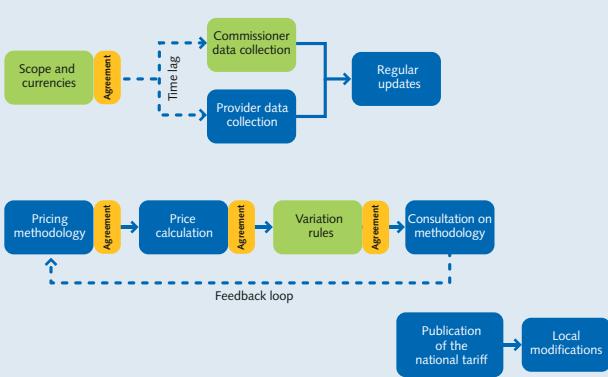
## Strategic development



**Description:** The part of the process that develops the direction on pricing strategy. The continuous work in this area would underpin the evolution of pricing of NHS services.

**Rationale:** The tariff would require development. In undertaking the development, it would be important for the NHSCB and Monitor to own the areas where they have expertise, but to work in a joined up way to ensure that the operational process runs quickly and smoothly.

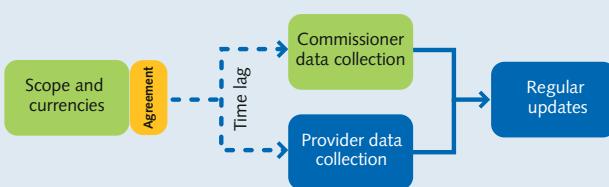
## Operational delivery



**Description:** This is the part of the process that would create the national tariff. There are various parts and inputs (including the strategic developments) to this process. These elements are further described below.

**Rationale:** This process has been designed to efficiently deliver the benefits of Monitor's independence and the relevant expertise of the organisations, such as the NHSCB's understanding of patient need and Monitor's understanding of provider costs and cost structures.

## Currency development



**Description:** This shows how currency development and changes in the scope of the national tariff would feed into data collection that would be used to update the underlying cost data. These data would then be used to calculate the national tariff.

**Rationale:** The NHSCB would lead currency development due to its clinical expertise and understanding of patient need. The NHSCB would also lead the collection of data on the commissioning side where it has authority. It is however Monitor that has the regulatory relationship with providers through the licence and would therefore lead in collecting data on the provider side.

## Methodology, prices and rules

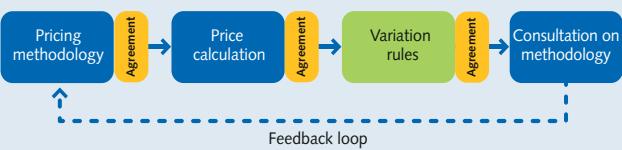


**Description:** This part of the process includes the development of the methodology (led by Monitor), the setting of prices (led by Monitor) and the setting of rules for variations in the national tariff (led by the NHSCB).

**Rationale:** Monitor's role is similar to that of other independent regulators that set prices. This is to set prices that enable the improvement of quality and efficiency of service provision. Monitor's role in this instance would also include leading on setting price adjustments like specialist top-ups.

The NHSCB's role in setting the variation rules reflects its expertise in designing patient care pathways and the desire to allow variations where they are appropriate from a patient care/clinical perspective.

## Consultation



**Description:** The outcome of the process above would form the basis of a consultation. Providers and commissioners will be given an opportunity at this stage to respond to the proposals set out by the NHSCB and Monitor. If enough disagree with the methodology (and methodology alone) Monitor would have to make changes or refer the methodology to the Competition Commission. This could result in changes to the methodology (and therefore prices) or finalisation of the proposals.

**Rationale:** The process of consulting on the methodology acts as an important part of the checks and balance on the pricing system and ensures that the views of providers and commissioners are accounted for when setting/changing the methodology. While the consultation is only on the methodology, it follows the setting of the actual prices and variation rules so that providers and commissioners are clear on the context of the methodology.

## Publication and price modifications



**Description:** Once the national tariff has been consulted upon and finalised, Monitor would publish the national tariff document. This document would set out in detail services, prices and rules for pricing of NHS services.

Following this publication, providers that do not feel adequately reimbursed for efficient costs would be able to make evidence based applications for a local modification to support continuity of service. The methodology for deciding whether to approve any local modification would be set out in the national tariff and consulted on in the above process.

**Rationale:** Publication of the national tariff is required towards the end of the process. However, for a number of reasons, some providers may require additional reimbursement to ensure the continuity of access of essential services.

# Annex 2

## Amendments to Part 3 of the Health and Social Care Bill

### Commons Committee

- We amended the Bill during Commons Committee to clarify that the national tariff would be a fixed price (not a maximum price) and that competition would be on the basis of quality and value. In this way, where services are subject to patient choice, patients would choose their preferred provider based on quality, access and other aspects of services most important to them – prices would be fixed in advance and money would follow patients' choices. Where competitive tendering is used for services not covered by the national tariff, then bids would be evaluated in terms of best value for patients, not on price alone – this is consistent with guidance on the procurement of NHS healthcare services published by the previous Government (March 2010).

### Committee post NHS Future Forum

- A number of amendments were made following the NHS Future Forum Report.
- Monitor's main duty remains as to "protect and promote the interests of people who use health care services". But in response to the concerns people raised during the Listening Exercise, it would no longer do this "by promoting competition where appropriate and through regulation where necessary".

Instead, Monitor would be expected to achieve its main duty: "by promoting provision of healthcare services which (a) is economic, efficient and effective, and (b) maintains or improves the quality of the services."

- There is a new duty on Monitor to: exercise its functions with a view to (a) preventing anti-competitive behaviour in the provision of health care services which is against the interests of people who use such services, and (b) enabling health care services for those purposes to be provided in an integrated way where this would improve quality for patients, improve equality of outcomes or access to services for patients or improve efficiency.
- New duties are placed on Monitor to involve people who used health care services and other members of the public in its work; and to make sure it takes appropriate clinical advice in carrying out its functions.
- An explicit duty on Monitor not to exercise its functions in order to increase or decrease the market share of any particular type of provider – whether public or private sector.
- Amendments to further prevent providers from 'cherry picking' services.
- Monitor would not, as originally proposed, have the power to open up access to one provider's facilities to another provider.

## **Commons Report**

- Amendments clarified Monitor's role in supporting commissioners to secure continuity of NHS services. Instead of designating in advance which services would be protected, at national level, commissioners would determine their requirements case by case.
- Monitor would support commissioners by regulating proactively to prevent providers from taking actions that would significantly undermine their continued ability to deliver NHS services.
- NHS Foundation Trusts would not be subjected to insolvency proceedings. Instead unsustainable Foundation Trusts would be addressed through a bespoke legal framework, based on existing legislation under the Health Act 2009.



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