Protecting and Promoting Patients’ Interests: 
the role of Sector Regulation

Executive Summary
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Introduction

1. The Health and Social Care Bill (the Bill) would put patients at the centre of decision-making, empower clinical commissioners to lead in improving outcomes and free NHS providers from bureaucratic controls. Part 3 of the Bill helps to enable this by establishing a comprehensive, proportionate legal framework for sector regulation in the NHS to protect patients’ interests.

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

* ‘NHSCB’ = NHS Commissioning Board; ‘CQC’ = Care Quality Commission
2. Effective sector regulation in healthcare is necessary to ensure that providers operate efficiently and in the interests of patients, both today and tomorrow. Our proposals build on Monitor’s existing role, as the regulator of Foundation Trusts, and complement the roles of the Care Quality Commission and NHS Commissioning Board. Each organisation would have distinct responsibilities, but their success would depend on effective cooperation and partnership. The Secretary of State would oversee these bodies and remain accountable to Parliament for securing the provision of a comprehensive health service for patients and delivering value for taxpayers’ money.

**NHS services would continue to be delivered by a ‘mixed economy’ of providers**

3. NHS services would continue to be delivered by a plurality of public, independent and voluntary sector providers. All NHS Trusts would be supported to become Foundation Trusts, and all Foundation Trusts would remain within public ownership.

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**Figure 2 – Commissioners decide when and how to use competition**

<table>
<thead>
<tr>
<th>Commissioner</th>
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<tr>
<td>Taking decision on where choice and competition for services is in the best interests of their patients</td>
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<td>Commissioners should consider relevant factors including:</td>
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<tr>
<td>• needs assessment and the priorities of patients and communities</td>
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<td>• the quality of existing services</td>
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<tr>
<td>• feedback from service users</td>
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<tr>
<td>• scope for quality and/or efficiency improvement</td>
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<td>• sustainability of existing service configurations</td>
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<td>• the levels of clinical risk</td>
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<tr>
<td>• the need to maintain continuity of service</td>
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<tr>
<td>• the potential benefits of integration</td>
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<tr>
<td>• the availability and capacity of providers</td>
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<tr>
<td>• the scope for patient choice and control</td>
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**Decision point**

- **Use any qualified provider**
  - Competition in the market
  - Accreditation

- **Use tendering**
  - Competition for the market
  - Frameworks

- **No competition**
  - Reconfiguration
  - Contract variations
  - Contract extension

**Taking into account**

- Secretary of State regulations on procurement and competition -
- The standing rules on patient choice
- NHS Commissioning Board guidance
- National tariff
- Rules on local pricing
Clinical commissioners lead in securing services to meet patients’ needs

4. Clinical commissioning groups would take the lead in arranging access to NHS services that meets patients' needs and for improving quality of care. The NHS Commissioning Board would commission some services directly and oversee commissioning at national level; it would have a duty to secure improvements in line with priorities set out in a ‘mandate’ from the Secretary of State.

5. Clinical commissioners will decide when and how to use competition as a means of improving services, within a framework of rules set by the Secretary of State and guidance from the NHS Commissioning Board. NHS services should be commissioned from the best providers. Regulations would ensure fairness and transparency of process, and require commissioners to be able to provide a clear rationale for their decisions.

The role of sector regulation is to protect and promote patients’ interests

6. We are not relying on market forces to ensure patients have access to the services they need and to drive improvements in quality and efficiency. Instead, our proposals for sector regulation aim to support the role of commissioners in securing better quality and value for money in the provision of NHS services by:

- securing the information that patients and commissioners need to make decisions about healthcare provision;
- strengthening incentives for providers and commissioners to act in the best interests of patients;

Figure 3 – Monitor’s core functions as sector regulator

- Economic, efficient, effective
- Competition, integration, pricing and continuity of services
- Regulations and licences

The right outcome
Promoting economic, efficient and effective healthcare services, whilst maintaining or improving quality in the interest of patients.

The right incentives
Using the right tools and levers to achieve the desired outcome – a fair, sustainable system that ensures patients receive high quality healthcare services.

The right foundations
Setting the rules and regulations for all providers and commissioners of NHS services to follow.
• maintaining rules to protect patients’ interests; and
• enforcing rules where necessary to protect patients’ interests.

Monitor’s role and functions as sector regulator

7. Chapter 1 (Part 3) defines Monitor’s overriding duty as, to protect and promote patients’ interests, by promoting economy, efficiency and effectiveness in the provision of healthcare services, whilst maintaining or improving quality.

8. Monitor’s duties would complement the duties on the NHS Commissioning Board, clinical commissioning groups and the Care Quality Commission, which Monitor would be required to have regard to. In addition, Monitor would have a duty to support commissioners by enabling the integration of services where this would improve quality or efficiency or help reduce health inequalities.

Monitor and the Care Quality Commission would operate a joint licensing regime in the interests of patients

9. Under the Bill, Monitor and the Care Quality Commission would operate a joint ‘licensing regime’, applicable to all providers of NHS services. To protect patient safety, it would be a prerequisite of holding a licence for a provider to maintain registration with the Care Quality Commission where required to do so. The Care Quality Commission would retain independent powers to inspect providers and take action to ensure patient safety.

10. Monitor would regulate providers through the licence to ensure minimum standards of governance and compliance with information requirements; and to set rules, on cooperation to improve quality, to support patient choice, and to enable integration. The licence would also enable Monitor to regulate prices, and to impose additional regulation to address anti-competitive conduct that acts against patients’ interests; and to secure continuity of NHS services.

Monitor and the NHS Commissioning Board would regulate prices in the interests of patients

11. Evidence demonstrates that regulating prices for healthcare services supports improvement in quality and efficiency and helps reduce transaction costs. Independent price regulation in healthcare has inherent benefits compared with the alternatives of, either: commissioners determining prices alone, which would be unfair on providers; or price competition, which could incentivise providers to cut costs at the expense of quality.

12. As set out in Chapter 4 (Part 3) our proposed approach would build on the national tariff system introduced by the previous Government and improve it by extending its scope and increasing transparency and independence in the tariff-setting process. Instead of the Department of Health setting the tariff, Monitor would regulate prices working jointly with the NHS Commissioning Board.
Monitor would oversee procurement and competition in the interests of patients

13. Chapter 2 (Part 3) sets out proposals for oversight of procurement and addressing anti-competitive conduct to protect patients’ interests. The aim is to ensure that services are commissioned from the best providers and that patients are given choice and control over their care, wherever possible.

14. There would be a comprehensive set of sector-specific rules – consistent with general procurement and competition law – applicable to the commissioners and providers of NHS services. These will be overseen by a sector regulator, Monitor. These will reflect the existing Principles and Rules for Cooperation and Competition in the NHS, introduced by the previous Government, which we will retain to demonstrate continuity.

Oversight of commissioners: ensuring transparency and value for money

15. Clinical commissioners would take the lead in securing services to meet patients’ needs and decide when and how to use competition as a means of improving quality and efficiency. Patients and the public should expect total transparency in the commissioning of services and for commissioners to justify their decisions in terms of quality and value for money. We have proposed secondary legislation under Part 3 to provide a framework of sector-specific rules for commissioners on:

- procurement;
- patient choice;
- anti-competitive conduct; and,
- managing conflicts of interest.

Figure 4 – Comprehensive, sector-specific rules on procurement and competition in healthcare, overseen by a sector regulator

Monitor (sector regulator)

The existing Principles and Rules for Cooperation and Competition

Regulations for commissioners

Licence conditions for providers*

Underpinned by

Procurement and competition law

*consistent with competition law which Monitor would have concurrent powers to apply instead of the OFT
16. These rules would give commissioners the full spectrum of procurement options and the onus would be on commissioners to use these tools in the interest of patients. These would include options for competitive tendering or competition based on patient choice, as well as options to commission services without competition, where appropriate. These rules would place the requirements of the existing Principles and Rules for Cooperation and Competition on a statutory footing and clarify their application to clinical commissioning groups. Monitor would oversee the rules to protect patients’ interests, consolidating the existing functions of the Cooperation and Competition Panel and some functions of Strategic Health Authorities.

Oversight of providers: addressing anti-competitive behaviour

17. Sector regulation has an important role in protecting patients’ interests against collusion and other abuses by powerful providers to restrict patient choice or distort competition against patients’ interests. This is consistent with the existing Principles and Rules for Cooperation and Competition, which would be placed on a statutory footing for providers through Monitor’s licensing regime. In this way the expectations of providers would be broadly the same as now.

18. These Principles and Rules are consistent with procurement and competition law. A problem with the current system, however, is that providers of NHS services may also be subject to competition law overseen separately by the Office of Fair Trading. The Bill proposes to address this by establishing concurrent powers for Monitor to apply the Competition Act 1998.

19. A key benefit of this approach is that competition law – where it applies – would be applied by a dedicated sector-regulator with greater knowledge and expertise of healthcare. Monitor would be well-placed to give guidance to providers and commissioners. Monitor may also be better placed than the Office of Fair Trading to identify where an arrangement that otherwise restricted competition resulted in overriding benefits to patients, such as the provision of services through a clinical network. This would help ensure that competition law is not applied inappropriately and only ever in the interests of patients.

Monitor and the NHS Commissioning Board would work together to secure continuity of services to protect patients’ interests

20. Chapter 5 (of Parts 3 and 4) sets out a framework for securing continuity of NHS services where a provider gets into difficulty. The proposals build on the existing regime for Foundation Trusts, established under the Health Act 2009, and improve that system by extending equivalent safeguards to secure continuity of NHS services provided by companies.

21. Monitor’s role would be to maintain an assessment of risk and support commissioners to secure continuity of services. Where a provider gets into difficulty, Monitor could intervene to support recovery and work with commissioners to secure continuity of services and agree appropriate contingency plans.
22. As a last resort, Monitor would have the power to appoint an administrator to take control of a provider and implement joint action with commissioners to secure continuity of services. Plans would be subject to public consultation and the Secretary of State would have right of veto where he considered that the commissioners or Monitor were failing to discharge their duties.

Risk Pool
23. Under Chapter 6 (Part 3) Monitor would have power to establish appropriate mechanisms for financing the costs of securing continuity of services. This will include powers to levy charges on commissioners and providers to contribute to a ‘risk-pool’. This would protect patients’ interests by ensuring that funding is available to sustain services during a period of administration.

Conclusion
24. The proposals in Part 3 would establish a comprehensive, proportionate and robust legal framework for sector regulation to protect patients’ interests. Key features:

- A clear focus on protecting and promoting patients’ interests
- Joint working between the Care Quality Commission, Monitor and NHS Commissioning Board
- A comprehensive system applicable to all types of provider
- Rationalisation of existing regulatory structures and reduced duplication
- The Secretary of State retaining overall accountability and powers to intervene where necessary

The proposed framework would be underpinned by secondary legislation (see table 1 opposite).
Table 1 – Current proposals to enact Regulations under Part 3 of the Bill

<table>
<thead>
<tr>
<th>Function</th>
<th>Clause</th>
<th>Parliamentary Procedure</th>
<th>Description</th>
<th>By when?</th>
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</thead>
<tbody>
<tr>
<td>Licensing</td>
<td>Clause 80</td>
<td>Negative resolution</td>
<td><strong>Definitions</strong> – identifying the ‘service provider’ that would be subject to the statutory requirement to hold a licence.</td>
<td>April 2013</td>
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<tr>
<td></td>
<td>Clause 82</td>
<td>Affirmative resolution</td>
<td><strong>Exemptions</strong> – determining exemptions from the requirement to hold a licence</td>
<td>April 2013</td>
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<tr>
<td></td>
<td>Clause 83</td>
<td>Negative resolution</td>
<td><strong>Exemptions</strong> – mechanisms for revoking or withdrawing exemptions.</td>
<td>April 2013</td>
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<tr>
<td></td>
<td>Clause 98</td>
<td>Affirmative resolution</td>
<td><strong>Licence modifications</strong> – objection percentage and share of supply threshold for referring disputed licence modifications to the Competition Commission</td>
<td>April 2013</td>
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<tr>
<td></td>
<td>Clause 103</td>
<td>Affirmative resolution</td>
<td><strong>Definitions</strong> – calculation of turnover</td>
<td>April 2013</td>
</tr>
<tr>
<td>Pricing</td>
<td>Clause 118</td>
<td>Affirmative resolution</td>
<td><strong>Pricing methodology</strong> – objection percentages and share of supply threshold for referring disputes over the pricing methodology to the Competition Commission.</td>
<td>April 2013</td>
</tr>
<tr>
<td>Commissioning</td>
<td>Clause 71–73</td>
<td>Negative resolution</td>
<td><strong>Commissioning regulations</strong> – requirements as to procurement, patient choice and competition and associated investigative and enforcement powers.</td>
<td>April 2013</td>
</tr>
<tr>
<td>(General)</td>
<td>Clause 135</td>
<td>Negative Resolution</td>
<td><strong>Risk pool (financing to secure continuity of services)</strong> – commissioner charges</td>
<td>April 2013</td>
</tr>
<tr>
<td></td>
<td>Clause 139</td>
<td>Affirmative Resolution</td>
<td><strong>Risk pool (financing to secure continuity of services) methodology for provider levies</strong> – objection percentage and the share of supply threshold for references to the Competition Commission.</td>
<td>April 2013</td>
</tr>
<tr>
<td>Continuity of Services</td>
<td>Clause 127–129</td>
<td>Affirmative resolution</td>
<td><strong>Health Special Administration</strong> – to make further provisions about health administration orders</td>
<td>April 2014</td>
</tr>
<tr>
<td>(Independent sector)</td>
<td>Clause 127(9)</td>
<td>Negative Resolution</td>
<td><strong>Health Special Administration</strong> – insolvency rules, subject to approval from Insolvency Rules Committee</td>
<td>April 2014</td>
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