

Liberating the NHS:

Regulating healthcare
providers

A consultation on proposals

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Description	The White Paper, Liberating the NHS, sets out a vision for an NHS centred around the needs of patients. One of the key features of the plans is to free providers from political interference and to establish a stable, transparent regulatory environment. This document sets out proposals to liberate providers from central Government controls and to develop Monitor as an independent economic regulator for health and adult social care.
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1. Introduction

- 1.1 The White Paper, *Equity and excellence: Liberating the NHS*, set out the Government's strategy for the NHS. Our intention is to create an NHS which is much more responsive to patients, and achieves better outcomes, with increased autonomy and clear accountability at every level.
- 1.2 *Liberating the NHS* makes clear the Government's policy intentions, and provides a coherent framework. Further work lies ahead to develop and implement detailed proposals. In progressing this, the Department will be engaging with external organisations, seeking their help and wishing to benefit from their expertise.
- 1.3 This document, *Regulating Healthcare Providers*, provides further information on proposals for foundation trusts and to establish an independent economic regulator for health and adult social care. It seeks views on a number of specific consultation questions.
- 1.4 This is part of a public consultation on implementation of proposals in the White Paper and supporting papers. The initial suite of supporting papers also includes:
 - Commissioning for Patients
 - Local Democratic Legitimacy in Health
 - The Review of Arm's-Length Bodies
 - Transparency in outcomes: a framework for the NHS
- 1.5 The Government will publish a response prior to the introduction of a Health Bill later this year.
- 1.6 With greater autonomy comes clearer accountability. Providers will be freed from control by hierarchical management. Instead they will be subject to effective quality and economic regulation, so that patients know the services are safe, and the taxpayer gets better value. Clinically-led commissioning, payment by results and choice will drive improvements in quality beyond essential regulatory standards.
- 1.7 *Regulating Healthcare Providers* considers potential additional freedoms for foundation trusts. It then considers the core purpose of Monitor in its changed

role as an economic regulator responsible for regulating prices, promoting competition, and supporting service continuity.

- 1.8 As an independent economic regulator, Monitor will carry out a range of regulatory functions currently delivered out, wholly or in part, by the Department of Health. The proposals aim to build on best practice in economic regulation. The Government is eager to receive comments on the proposed model of regulation as well as on the more detailed questions in this document. We intend to refine our proposals in light of responses to this consultation and further analysis of evidence from other sectors, working closely with the Department for Business, Innovation and Skills. We will consider development of Monitor as an economic regulator for healthcare in the wider context of the operation of sectoral regulation and concurrent application of competition law by different regulatory authorities.

2. Freeing Providers

- 2.1 The Government's intention is to free providers so that they can focus on improving outcomes, be more responsive to patients, and innovate. In doing this, we will build on the overall success of the foundation trust model, whilst recognising, through our plans for stronger quality regulation, and patient and public voice, that failings have occurred in some organisations.
- 2.2 The Coalition's belief is that the natural condition of organisations ought to be one of freedom rather than being shackled. In this way we will support organisations to develop and mature; they will be accountable but not infantilised. The Government's approach is that where specific control mechanisms are needed for providers, these should in general take effect through regulatory licensing and clinically-led contracting, rather than hierarchical management by regions or the centre. All providers of NHS care should be able to compete on a level playing field, so that they succeed or fail according to the quality of care they give patients and the value they offer to the taxpayer.
- 2.3 The White Paper set out our ambition to create the largest and most vibrant social enterprise sector in the world. The Government's intention is to free foundation trusts from constraints they are under, in line with their original conception, so they can innovate to improve care for patients. In future, they will be regulated in the same way as any other providers, whether from the private or voluntary sector. Patients will be able to choose care from the provider they think to be the best. For many foundation trusts, a governance model involving staff, the public and patients works well. But we recognise that this may not be the best model for all types of foundation trust, particularly smaller organisations such as those providing community services. As set out below, we are consulting on future requirements: we envisage that some foundation trusts will be led only by employees; others will have wider memberships. The benefits of this approach will be seen in high productivity, greater innovation, better care and greater job satisfaction. Foundation trusts will not be privatised.
- 2.4 This section seeks your views on options for increasing foundation trusts' freedoms while ensuring financial risk is properly managed.
- 2.5 As made clear in the White Paper, within three years, we will support all NHS trusts to become foundation trusts. It will not be an option for organisations to decide to remain as an NHS trust rather than become or be part of a foundation

trust and in due course, we will repeal the NHS trust legislative model. A new unit in the Department of Health will drive progress and oversee SHAs' responsibilities in relation to providers. In the transition period to the new system, Monitor will continue to apply its current standards to those organisations applying to become Foundation Trusts.

- 2.6 In the event that a few NHS trusts and SHAs fail to agree credible plans, and where the NHS trust is unsustainable, the Secretary of State may as a matter of last resort apply the trust administration regime introduced by the Health Act 2009. From April 2013, Monitor will take on the responsibility of regulating all providers of NHS care, irrespective of their status. Financial control will be maintained during the transition, with the Department, Monitor and SHAs taking any necessary steps.
- 2.7 As made clear in the White Paper, special statutory arrangements will be made for the three high secure psychiatric hospitals (Broadmoor, Rampton and Ashworth) allowing them to become foundation trusts and benefit from the independence of foundation status while retaining appropriate safeguards to reflect their role in the criminal justice system.

Continuity and additional potential freedoms for foundation trusts

- 2.8 We will keep the legislative framework for foundation trusts so they will continue to have a unique legal form. Their principal purpose will continue to be the provision of goods and services to the health service in England. As made clear in the White Paper, their broad statutory framework will continue to ensure that any surplus, and any proceeds from the sale of assets, are reinvested in the organisation or used to repay debt, rather than distributed externally, so that patients reap the benefits.
- 2.9 It is within this context that we are seeking views on liberalising the foundation trust regime. Foundation trusts are already effectively social enterprises – organisations with a social purpose that use any surpluses in pursuit of their purpose. They will continue to provide services to the NHS, with staff enjoying greater flexibility and freedom to deliver better services for patients.

Private income

- 2.10 In developing the model for foundation trusts the previous government imposed an arbitrary, ill-thought-through cap on their private income, fixed at the percentage of their income from private sources before the organisation

became a foundation trust. The perverse consequences include the inability in practice of an internationally respected organisation such as Great Ormond Street to expand the services it can offer for the benefit of patients; and the inability of the NHS to take proper advantage, for the benefit of this country, of the power of its brand abroad.

- 2.11 During the passage of the Health Act 2009, the House of Lords sought to rectify this anomaly. The previous government instigated a review of the cap and eased restrictions that had prevented mental health foundation trusts from providing services that are not directly funded by the NHS, including contributing to return-to-work programmes. This Government will bring forward provisions to address this anomaly for all foundation trusts by repealing the cap. This will allow foundation trusts to broaden the scope of their activities, whilst maintaining their primary purpose of providing NHS services.

Q1. Do you agree that the Government should remove the cap on private income of foundation trusts? If not, why; and on what practical basis would such control operate?

Statutory borrowing limits

- 2.12 Foundation trusts are already free to borrow from banks and other private sector lenders to improve the facilities and equipment available to patients. But they are subject to statutory controls – unlike voluntary or private providers – which give Monitor powers to set limits on the amount they can borrow. This was intended to prevent them from borrowing irresponsibly. However, since the first foundation trusts were authorised in 2004, none has taken a loan from the private sector for a significant capital investment as far as we are aware. And the new system of economic regulation, including price setting and failure, will provide strong incentives for financial discipline. In light of this, the Government is considering whether it will remain relevant in the future to maintain statutory controls over foundation trusts' borrowing limits.

Q2. Should statutory controls on borrowing by foundation trusts be retained or removed in the future?

Changing the constitution and configuration of a foundation trust

- 2.13 At the moment, foundation trusts need the specific consent of the regulator, Monitor, to amend their own constitutions. The Government does not see this

as necessary. We want to allow foundation trusts to change their constitutions with the consent of their boards of governors and directors, replacing the current requirement to obtain the consent of the regulator with more robust internal checks. In making any changes, foundation trusts will still need to ensure that their constitution is consistent with the legal form prescribed in legislation. Monitor, in its new role - described in this document - as the regulator for all of health and social care in England, will license all relevant providers of NHS services and will need to know that they are legally constituted and have clear governance arrangements. Foundation trusts would still, therefore, be required to notify Monitor of changes to their constitutions, although this would not be subject to regulatory approval.

Q3. Do you agree that foundation trusts should be able to change their constitution without the consent of Monitor?

2.14 We want to create a dynamic and innovative provider sector in which foundation trusts can choose how best to evolve and organise themselves and co-operate. They should be able to consider how they work with other foundation trusts and NHS trusts or indeed to reconfigure their organisation, and perhaps even be able to separate part of it, if they think that appropriate. Alongside joint ventures, alliances, federations and other forms of co-operation, we want to ensure it is possible for a successful foundation trust to acquire another organisation or to de-merge. We want these organisations, with their focus on providing services to the NHS, to be able to combine where they consider this will make them more effective. So we will legislate to remove any unnecessary barriers. We will make it easier for a foundation trust to merge with or acquire another foundation trust or NHS trust, or de-merge, ensuring the law allows this and that legal requirements about a foundation trust's legal status, elections and appointments do not get in the way inappropriately. Like other organisations, NHS Trusts and Foundation Trusts will be subject to merger controls to protect competition (see paragraphs 66 to 68 below).

Q4. What changes should be made to legislation to make it easier for foundation trusts to merge with or acquire another foundation trust or NHS trust? Should they also be able to de-merge?

Governance

2.15 The unique governance structure of foundation trusts seems to be working in many places. It requires all foundation trusts to adopt a three-tier model of members, governors and directors, with specific statutory requirements

regarding the make up of a foundation trust's membership, the composition of its boards of governors and of directors, and the relationships between them.

- 2.16 The Government has no intention of requiring or encouraging any existing foundation trust to change its governance model. It also wants NHS trusts to continue to prepare to take on the existing foundation trust model. However, we are interested in exploring whether there would be benefit in allowing some additional flexibility to foundation trusts, for example to increase staff influence.
- 2.17 Our assumption is that flexibility to adapt governance to suit an organisation's particular circumstances could be available for some foundation trusts, with the consent of their governors. Such flexibility could be available for all or only for some organisations such as more mature foundation trusts that have, through operating with the existing governance model for some time, adapted to looking outwards for their accountability. Allowing flexibility for foundation trusts that have existed for over, say, three years, would emphasise the need for them to build effective relationships with existing governors and make a convincing case for any change. We could consider limiting the scope of this flexibility, for example to ensure that the public can be members and have a seat amongst the governors.
- 2.18 In addition, *Liberating the NHS* said that some foundation trusts could be led only by employees, for example smaller organisations such as those providing community services. The strength of the case for the public (and patients) to form a majority on the board of governors at the outset may vary depending on the organisation involved. It may be possible to define a sub-group of providers that could be allowed to adopt a staff-only membership model from the start of their existence as foundation trusts. For example, this option could be available to organisations that only provide community services or to those that have few capital assets that were paid for by the taxpayer, below a specified threshold.
- 2.19 Strong governance is of key importance for corporate success, financial control, public accountability and stability. For these reasons well designed governance structures are important. There may be arguments for changing the governance arrangements of FTs, but we are also aware that there are risks. Given the regulatory controls we propose to remove, it may be helpful to increase the accountability of an organisation to its governors, for example by allowing them to call a special general meeting, ensuring they are invited to an annual general meeting which receives a report on executive pay and requiring a special general meeting to approve any significant transactions.

Q5. What if any changes should be made to the NHS Act 2006 in relation to foundation trust governance?

Taxpayer investment in foundation trusts

2.20 In addition to securing the continuity of provision, the taxpayer has an interest in foundation trusts through public dividend capital and loans owed to the Department of Health. Should foundation trusts fall into financial failure, this could necessitate writing off some element of this investment, which has an associated cost for the Department of Health. Therefore, it is important that the management of this stake in foundation trusts be undertaken in a way to minimize the risk and costs of any such failure. The future form of this investment and its management should as far as possible be conducted on a commercial basis to ensure that it does not lead to undue interference with foundation trust freedoms.

2.21 Under the current regime, Monitor has a role in managing these risks. However, as we move to a system where all providers are regulated on the same basis by Monitor, and not controlled by the Department of Health, it will be important for Monitor acting as economic regulator to avoid having a special interest in - or giving preferential treatment to – foundation trusts as a group of providers, compared with any other group of providers. In future, the role could be undertaken in the Department or a third party working on behalf of the Department - this could include Monitor if the independence of the regulator role is maintained.

Q6. Is there a continuing role for regulation to determine the form of the taxpayer's investment in foundation trusts and to protect this investment? If so, who should perform this role in future?

Further issues

2.22 This section of *Regulating Healthcare Providers* has described some of the options for increasing foundation trust freedoms, and potential changes to the foundation trust legislative framework given the introduction of economic regulation. It is by no means comprehensive and the Government would welcome additional comments and proposals.

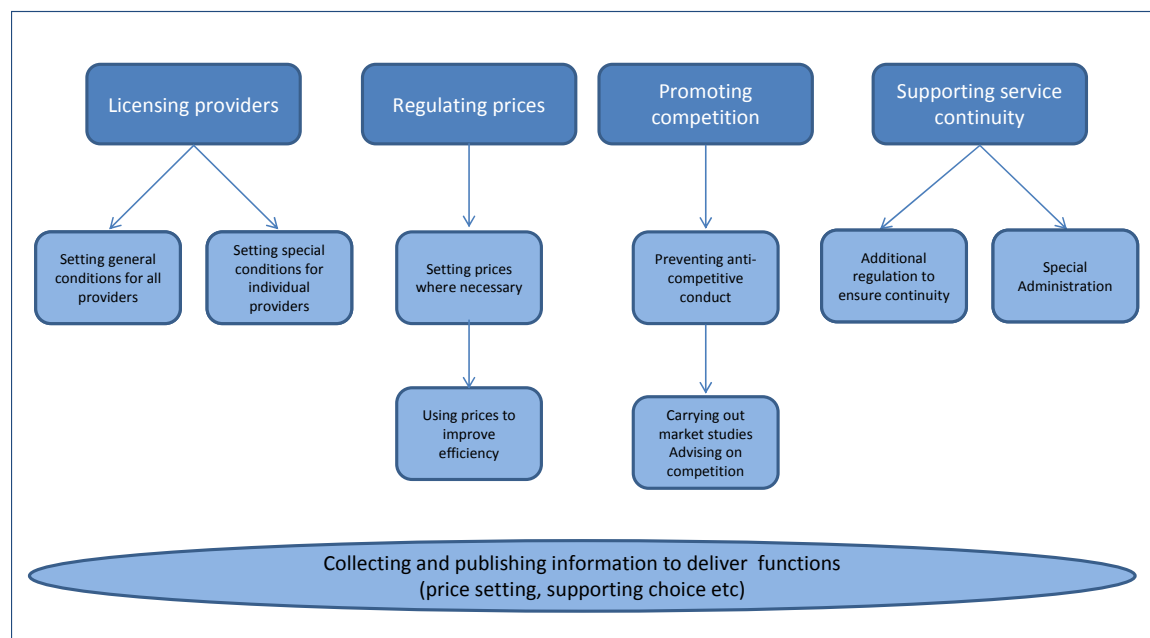
Q7. Do you have any additional comments or proposals in relation to increasing foundation trust freedoms?

3. Economic regulation

- 3.1 *Liberating the NHS* made clear that the Government proposes to introduce a system of independent economic regulation to sit alongside independent quality regulation. As we move away from a system of top-down performance management, the rationale for economic regulation is to protect the public interest in the provision of services, particularly where communities are highly dependant on one, or very few, providers. Furthermore, as we seek to offer patients choice of ‘any willing provider’ for most services, the benefit of our approach is the ability to address potentially anticompetitive behaviour, through regulation where appropriate, rather than through costly legal proceedings. In developing this, we are learning from models in other countries and other sectors such as energy and water, whilst applying these models to the particular circumstances, values and principles of the NHS in England.
- 3.2 Our proposals will set providers free while at the same time protecting the public interest. Monitor will be developed into the economic regulator for all of health and adult social care in England. Monitor’s principal duty will be to protect the interests of patients and the public in relation to health and adult social care services, by promoting competition where appropriate, and through regulation where necessary. Monitor will be required to exercise its functions in a manner consistent with the Secretary of State’s duty to promote a comprehensive health service in England and have regard to the following objectives:
- maintaining the safety of patients and individuals accessing services
 - securing ongoing improvements in quality of care
 - providing equitable access to essential health and adult social care services
 - supporting commissioners in maintaining continuity of essential services
 - securing ongoing improvements in the efficiency of services
 - promoting appropriate investment and innovation
 - making best use of limited NHS and adult social care resources.

- 3.3 Monitor will license providers of NHS services in England and exercise functions in three areas: regulating prices, promoting competition and supporting service continuity. Its statutory remit will be limited to the provision of health and adult social care services. We do not envisage that it will extend to regulating supply of products or technologies such as equipment or pharmaceuticals.
- 3.4 In carrying out its functions, Monitor will need to balance multiple objectives, which may at times come into conflict. For example, the public interest in maintaining access to services in remote or rural areas may need to be considered against objectives to improve efficiency or promote competition. Monitor will be required to act transparently in determining its approach to regulation and in its decisions in individual cases. Where it appears to Monitor that any of its duties conflict with each other in a particular case, it will need to take a balanced judgement and set out a clear rationale for its decision. Building on established practice in other sectors, the rationale will need to set out where objectives come into conflict, the nature of the conflict, and Monitor’s justification for prioritising between objectives in reaching its decision.

MONITOR’S CORE FUTURE FUNCTIONS



- 3.5 Monitor will continue to have the status of a non-departmental public body (NDPB), just like the Care Quality Commission and, in future, the NHS Commissioning Board. The Secretary of State will not have powers to direct Monitor in carrying out its functions; this maintains the current position and is

consistent with principles of effective regulation. We envisage that the Secretary of State will retain the power to appoint the Chair of Monitor for a term of four years and we propose that he should also have power to approve the appointment of a Chief Executive, who would be nominated by the Chair. Consistent with existing arrangements, the Secretary of State would have further powers to remove the Chair or Chief Executive, during their terms, for reasons of incapacity or misbehaviour.

- 3.6 As an NDPB, Monitor will be required to account to central Government for the use of its resources and to publish annual accounts. In addition, Monitor will be required to report annually to Parliament to demonstrate value for public money and will be accountable to the public through Parliamentary scrutiny, including through investigations by select committees. Monitor's funding position will be agreed with H.M. Treasury as part of the spending review process.
- 3.7 Monitor's regulatory decisions will be subject to a range of further checks and balances. These will include obligations to consult with interested parties – such as the NHS Commissioning Board and providers - and to carry out impact assessments of the costs and benefits of new regulation. Parties will also have the ability to appeal against Monitor's licensing and pricing decisions in particular circumstances.
- 3.8 We are committed to reducing the overall burdens of regulation across the health and adult social care sectors. In line with the principles of better regulation, Monitor will be under a duty ensure that its regulatory activities are transparent, proportionate, consistent and targeted only at cases where action is needed.
- 3.9 Before introducing new regulation (other than applying competition law), Monitor will be required to carry out a regulatory impact assessment and demonstrate that the new regulation is necessary. It will also need to demonstrate that it would not be able to protect patients and taxpayer's interests through less burdensome forms of intervention such as application of competition law on a case by case basis. Monitor will be required to review its activities as choice and competition develop and to reduce regulation wherever possible over time.

4. Licensing

- 4.1 This section sets out the role of Monitor in licensing providers of NHS services. In the new system, the CQC and Monitor will be jointly responsible for administering an integrated and streamlined registration and licensing regime.
- 4.2 The CQC currently registers providers of health and adult social care services to provide assurance that they meet essential levels of quality and safety. It will continue to play an important role in the new system, carrying out inspections in relation to its registration requirements and taking enforcement action where needed. The CQC will also continue to work closely with OFSTED, the lead inspectorate for children's social care, on matters relating to inspection of children's health services.
- 4.3 In future, Monitor will also need to license some providers of NHS services as a mechanism for delivering its regulatory functions. For example, it will need to license providers and set licence conditions to ensure that information is collected to set prices, promote competition, and safeguard the continuity of additionally regulated services. This will supersede and replace elements of Monitor's existing authorisation and compliance regime. It will be a requirement of Monitor's licence that organisations have gained CQC registration.
- 4.4 The CQC and Monitor will retain separate responsibilities for their parts of the regime. This means that the CQC will continue to register providers of health and adult social care. Meanwhile, Monitor will license providers of NHS healthcare services. Our aim is for a streamlined process that helps to minimise bureaucracy and ensures that regulation of providers is proportionate. Both regulators will need to work together to develop streamlined procedures.
- 4.5 As explained in the White Paper, Monitor's powers to regulate prices and license providers will only cover NHS services. Providers of other care services, including adult social care, would still be required to register with the CQC but would not be required to hold Monitor's licence. The rationale for this is that there is limited choice of alternative providers for many NHS services and some communities are highly dependent on one, or very few, providers. In adult social care and private healthcare, there are already mature markets with a range of choice between alternative providers.

Q8. Should there be exemptions to the requirement for providers of NHS services to be subject to the new licensing regime operated by Monitor, as economic regulator? If so, what circumstances or criteria would justify such exemptions?

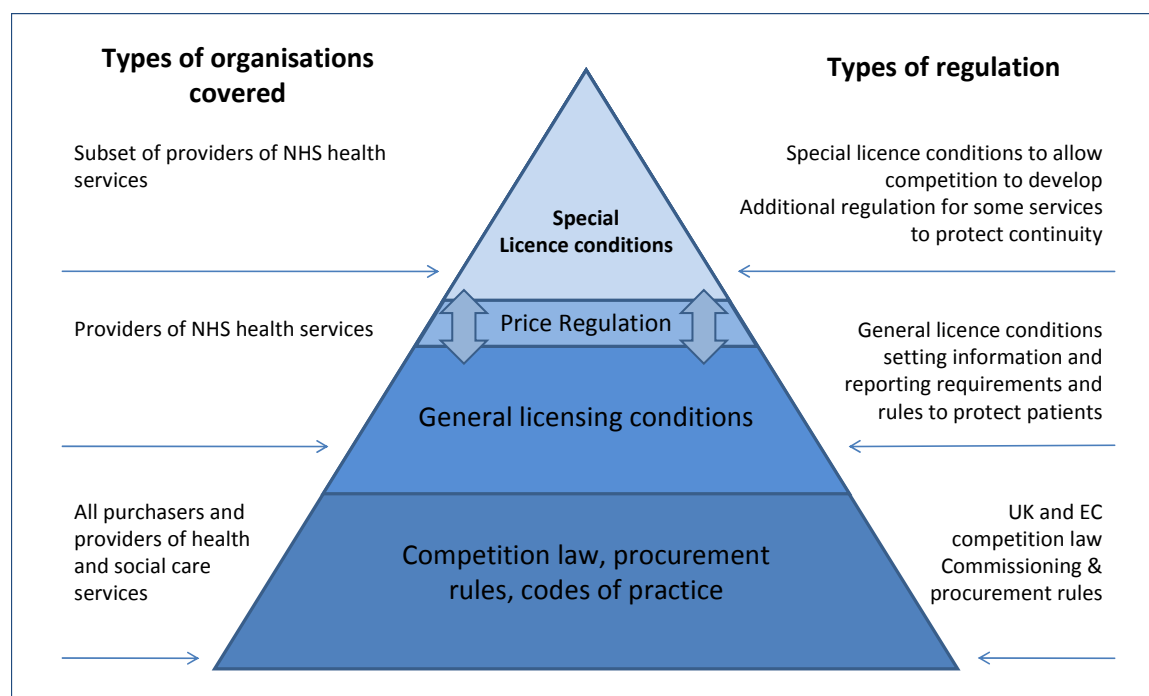
4.6 Monitor will be responsible for developing a general licence setting out conditions for all relevant providers of NHS services. The general licence conditions are likely to include a requirement that an organisation is a fit and proper body to provide NHS services - for example that it is a recognised legal body, with a properly constituted board, clear governance arrangements and a business plan. We envisage this replacing Monitor's current role in authorising foundation trusts. However, Monitor is likely to continue to act as the registrar for foundation trusts, to ensure that foundation trusts are legally constituted (in line with statutory requirements) and to maintain basic information such as membership of their boards.

4.7 The general licence conditions are also likely to include: requirements to provide Monitor with details on provision of NHS services, to notify proposed changes to services, and to report information (for example data on costs and volumes needed to set prices for some services). (In practice this information may be collected by the Health and Social Care Information Centre on behalf of Monitor.) The licence may also include other rules to protect patients' and taxpayers' interests (for example rules on advertising and mis-selling).

4.8 In addition, Monitor will be able to set special licence conditions for individual providers in certain cases. Monitor will be able to set special licence conditions either because a provider enjoys a position of market power in a local area or because there is a need for additional regulation to protect service continuity. The special licence conditions could include additional requirements on providers to promote choice (for example requirements to provide certain services to competitors) or requirements to protect continuity of services (for example requirements to pre-notify the regulator of plans to stop providing the service).

Q9. Do you agree with the proposals set out in this document for Monitor's licensing role?

THREE TIERS OF ECONOMIC REGULATION FOR HEALTH AND SOCIAL CARE



Enforcement powers

- 4.9 Monitor will have a range of powers to ensure that providers comply with their licence conditions. These will include the power to fine providers for failing to comply with licence conditions. They may also include the power to suspend or revoke a licence for failure to comply with its conditions.

Appeals against licence modifications

- 4.10 Monitor will have an obligation to review the need for and functioning of the general and special licence conditions on a periodic basis. It will also have powers to modify general licence conditions or individual providers' special licence conditions either to address new problems or reduce regulation. We envisage that groups of providers will have the right to appeal to the Competition Commission if a significant proportion oppose Monitor's proposed changes to the general licence conditions. Individual providers will have the right to appeal regarding proposed changes to their special licence conditions.

Q10. *Under what circumstances should providers have the right to appeal against proposed licence modifications?*

Fees

- 4.11 Monitor will need appropriate resources in order to carry out its functions. Monitor currently receives funding in the form of grant-in-aid from central Government. However, it also has statutory powers (as yet unused) to raise funds from the foundation trusts it regulates by charging fees.
- 4.12 In general, it is good practice for regulators to raise the majority of their funding from their industries rather than receiving funding in the form of grants from central government. This ensures that the regulator has true independence from central Government. It also ensures that the providers subject to regulation pay directly for that oversight, and that the regulator has an incentive to ensure that regulation is proportionate and avoids imposing unnecessary burdens. We therefore propose that Monitor should fund its regulatory activities for licensed providers by charging fees and receive grant-in-aid from if needed to support other activities.

Q11. Do you agree that Monitor should fund its regulatory activities through fees? What if any constraints should be imposed on Monitor's ability to charge fees?

5. Price regulation and setting

- 5.1 In our healthcare system, prices are set for a range of services under national tariffs. Up until now, the Secretary of State has been responsible for setting these prices on an annual basis. In other sectors, Government has delegated responsibility for price setting to independent economic regulators. Such bodies can create a more stable environment and greater regulatory certainty so that providers have the confidence to make long-term investments in services. Independent regulators can also develop strong technical skills in setting prices at the right levels.
- 5.2 As explained in the White Paper, Monitor will be responsible for setting efficient prices, or maximum prices, for NHS-funded services, in order to promote fair competition and drive productivity. Monitor and the NHS Commissioning Board will need to work closely together in deciding which services should be subject to national tariffs, and in developing appropriate currencies for pricing and payment purposes. Currencies will identify units of services for payment purposes and may have a direct impact upon incentives. For example, where currencies and payments are based on throughput of diagnostic or surgical procedures this may create financial incentives for providers to increase volumes of those procedures. As set out in the White Paper, we envisage the Board having primary responsibility for determining appropriate currencies. There may also be a role for Monitor, in setting tariff structures, to ensure that currencies do not restrict or distort competition against the public interest.
- 5.3 Monitor's role will be to set prices or price caps for services subject to national tariffs. Monitor will be responsible for devising a pricing methodology. It will be required to run a public consultation process, engaging with both the NHS Commissioning Board and providers. The tariff-setting methodology should be made transparent and fully open to scrutiny. As at present, the methodology will need to take account of inflation and, over time, the tariffs will be adjusted on a bottom-up basis to reflect increases in provider efficiency. In addition, Monitor will be under a duty to have regard to the need to make best use of limited NHS and social care resources, although primary responsibility for managing within the limits of these resources will be for the Board and local commissioners.

Q12. How should Monitor have regard to overall affordability constraints in regulating prices for NHS services?

- 5.4 It is important that both purchasers and providers are able to challenge aspects of Monitor's pricing decisions. The NHS Commissioning Board will be able to appeal to the Competition Commission if it opposes Monitor's methodology for setting tariff prices. Providers will also have the right to appeal to the Competition Commission, although it will be important to avoid perverse incentives to make vexatious or trivial complaints.

Q13 Under what circumstances and on what grounds should the NHS Commissioning Board or providers be able to appeal regarding Monitor's pricing methodology?

- 5.5 In exceptional circumstances, it may be necessary to modify the tariff price to sustain the provision of services. In rare cases, a provider might unavoidably have higher costs than other organisations, for example because it operates in a rural location and provides key services to a small, isolated population. We therefore propose that Monitor should have powers to modify tariffs for individual providers on rare occasions. For example, Monitor might set higher prices for a provider where it was the only provider of key services in an area, where it had unavoidably higher costs, and where there were no other providers able to enter the market and offer the service within the tariff price.
- 5.6 In carrying out this function, Monitor would need to have regard to its duties to protect the interests of patients and the public, through competition where appropriate and through regulation where necessary. It would also need to have regard to its duty to promote efficiency. In particular, it would need to ensure that any modifications to the tariff did not give recipient providers an unfair competitive advantage or constitute unlawful state aid under EU rules.
- 5.7 Commissioners and providers will be able to apply to Monitor to set a differentiated price or arbitrate in some pricing disputes. Monitor will need to consult the Board on proposed variations to tariff prices in individual cases.
- 5.8 Monitor and the NHS Commissioning Board will need to work closely together when developing tariffs and prices. They will be under an obligation to consult with each other on the services subject to national tariffs, contract currencies and funding models. Monitor will need to consult with the Board on its proposed methodology and prices for services under national tariffs. It will also need to consult with the Board on proposals to agree variations to the tariff in individual cases and in relation to some pricing disputes. The Department of Health, given the overall accountability of the Secretary of State for the NHS, and acting as sponsor of both the Board and the regulator,

will have a responsibility for promoting effective working behaviours between the Board and the regulator.

Q1. How should Monitor and the Commissioning Board work together in developing the tariff? How can constructive behaviours be promoted?

6. Promoting competition

- 6.1 In future, patients will have more clout in the system, more control over their care and the ability to choose between any willing provider for most services. Choice will spur providers to become more responsive to patients' needs, stimulating innovation, improvements in the quality of care and increases in productivity. It will be necessary to take proactive steps to make patient choice a reality. This needs to include providing patients with information to make informed decisions and making it easier for new providers to offer services. There will be a need for ongoing regulatory oversight to promote competition and ensure that it delivers the intended benefits for patients and taxpayers.
- 6.2 The Government will create a presumption that all patients will have choice and control over their treatment and choice of any willing provider, wherever relevant. In the new system, the NHS Commissioning Board will have a duty to promote patient choice, including developing the NHS choice offer in accordance with its mandate from the Secretary of State. The Board will also maintain guidance to commissioners on the procurement of health services.
- 6.3 As explained in the White Paper, we propose that, in carrying out its functions, Monitor would have a duty to promote competition, where appropriate. Specifically, Monitor would have powers to impose remedies and sanctions to address restrictions on competition, through its licensing regime, and through concurrent powers with the Office of Fair Trading (OFT) to enforce key aspects of competition law.

ROLES OF MONITOR AND NHS BOARD IN PROMOTING COMPETITION

Role of NHS Commissioning Board	Role of Monitor	Role of other organisations
<ul style="list-style-type: none"> • Promoting patient choice • Deciding how to introduce choice of any willing provider • Developing standard NHS contracts • Establishing guidance on commissioning and procurement • Assessing complaints on commissioning / procurement 	<ul style="list-style-type: none"> • Setting licence conditions to prevent anti-competitive behaviour / facilitate development of competition • Investigating anti-competitive conduct under Competition Act 1998 • Carrying out studies and referring malfunctioning markets to the Competition Commission • Investigating complaints about commissioning after referral to NHS Board • Providing advice to Government and NHS Board on barriers to competition / level playing field 	<ul style="list-style-type: none"> • Secretary of State sets mandate for NHS Board • OFT has concurrent powers to investigate anti-competitive conduct under Competition Act 1998 • Competition Commission investigates barriers to competition in markets following reference • OFT and Competition Commission investigate and prevent anti-competitive mergers

Preventing anti-competitive behaviour

- 6.4 The OFT currently has powers to enforce the Competition Act 1998 in health and social care. It also has the ability to carry out studies of health and social care services and to refer them to the Competition Commission. Given that Monitor will play a key role in promoting competition, we propose that it should have concurrent powers with the OFT to apply the Competition Act in addressing restrictions on competition in the health and adult social care sectors.
- 6.5 We propose that Monitor should also be able to carry out ‘market studies’ to investigate markets where competition is not functioning properly, for example because there are structural problems or other barriers to effective competition. It will be able to advise Government and the NHS Commissioning Board on changes to allow competition to function effectively. It will also have powers to refer dysfunctional markets or barriers to competition to the Competition Commission for investigation.
- 6.6 Application of Monitor’s powers to enforce competition law within the health and social care sectors will not be limited to providers required to hold a licence. The rationale for this is that providers may deliver a mix of NHS and private healthcare, as well as other care services. The regulator would not be

able to police the system effectively if there were arbitrary distinctions preventing it from investigating issues spanning these different activities. This means that Monitor will have powers to enforce competition law and impose sanctions and remedies in relation to providers of health or adult social care services irrespective of whether they are required to hold a licence.

- 6.7 Monitor will have the power to set general licence conditions for all licensed providers. These may include provisions to protect patients' and taxpayers' interests such as rules to prevent misleading advertising or selling.
- 6.8 In some local areas, incumbent providers may be in a powerful position and have the ability to prevent choice and plurality developing. We therefore propose that Monitor should also have powers to set special licence conditions for some individual providers to protect competition. These special licence conditions might include: requirements to accept services such as diagnostic tests from other providers where clinically appropriate; requirements for providers to publish their terms and conditions for providing services to other providers; or requirements covering a provider's capital expenditure in certain circumstances.

Q15. Under what circumstances should Monitor be able to impose special licence conditions on individual providers to protect choice and competition?

Ensuring a level playing field

- 6.9 Where there is competition, this will be on a level playing field that rewards the highest-quality, most efficient providers that continuously improve services in line with the needs and the preferences of the patients they serve. The regulator will be able to consider factors that may put particular providers at a relative disadvantage and make proposals to the Government or the NHS Commissioning Board to move over time to ensure that any differences are fair.

Q16.. What more should be done to support a level playing field for providers?

Joint working with the NHS Commissioning Board

- 6.10 Monitor and the NHS Commissioning Board will need to work closely together to promote patient choice and plurality. The Board will have a duty to promote and extend choice and patient control and involvement in services. It will be responsible for developing and agreeing with the Secretary of State

guarantees for patients about the choices they can make and for setting out its strategy for delivering these. There will be a requirement to consult Monitor on this. Monitor will also give public advice to the NHS Commissioning Board on wider issues relating to choice and competition.

Anti-competitive behaviour by commissioners

6.11 In the current system, the Department of Health has issued guidance to commissioners on the procurement of health services and rules to prevent anti-competitive conduct. The Department's Cooperation and Competition Panel is able to investigate complaints regarding commissioners' procurement decisions and anti-competitive conduct. It can advise the Secretary of State or Monitor on these cases but has no enforcement powers.

6.12 For the future, we propose to set out in legislation the duties of the NHS Board and commissioners to promote choice, to act transparently and non-discriminatorily in all commissioning activities, and to prohibit agreements or other actions to restrict competition against patients' and taxpayers' interests. Monitor will have powers to investigate and remedy complaints regarding commissioners' procurement decisions, or other anticompetitive conduct, acting as arbiter.

Q27. How should we implement these proposals to prevent anti-competitive behaviour by commissioners? Do you agree that additional legislation is needed as a basis for addressing anticompetitive conduct by commissioners and what would such legislation need to cover? What problems could arise? What alternative solutions would you prefer and why?

Regulation of mergers

6.13 As well as preventing anti-competitive behaviour, it will be important to regulate mergers to maintain sufficient competition in the public interest. The OFT and Competition Commission are responsible for regulating mergers in all sectors under the Enterprise Act 2002. They can already assess mergers in health and social care under the Act and the OFT has done so on a number of occasions. In the future, we envisage that the OFT and Competition Commission will be the sole organisations with responsibility for investigating mergers in health and social care services. We expect Monitor to offer the OFT and Competition Commission any assistance and advice in investigations in the sector, as they may reasonably require.

6.14 We may need to legislate to ensure that the full range of providers of NHS services are subject to appropriate merger controls. We are considering the need for modifications to the Enterprise Act 2002 to take account of the specific characteristics of mergers in healthcare, including whether there is a case for:

- Any modifications to ensure that the full range of providers of NHS services, including NHS trusts and foundation trusts, are subject to merger controls; and
- Powers for the Secretary of State for Business Innovation and Skills to intervene in mergers on public interest grounds

6.15 Over the last two years, alongside this statutory regime, the Department of Health's Cooperation and Competition Panel has also provided expert advice to the Secretary of State and Monitor on mergers involving NHS Trusts and foundation trusts. The Panel will continue to provide expert advice on these mergers during the transition to the new system.

7. Supporting continuity of services

- 7.1 Ensuring the continuity of essential public services is vital to individuals and communities. There will be a range of safeguards in the new system to ensure the continuity of care, even when the providers of services may change. The objective of these measures is to ensure that there is a smooth transfer if commissioners wish to replace existing services with better alternatives, or to ensure service continuity should a provider become insolvent. This section sets out how this will work under the proposed reforms.

The role of commissioners

- 7.2 In future, consortia of GP practices will commission the vast majority of NHS services for their patients, including elective hospital care, rehabilitative care, urgent and emergency care, most community services, and mental health services. As in the current system, commissioners will retain primary responsibility for ensuring the continuity of service provision. This can be achieved through a variety of approaches including: seeking to commission services from a broad range of providers; encouraging the development of new and innovative types of provision; and, where necessary, negotiating contractual arrangements with providers that ensure the continuity of services, such as notice periods that are sufficiently long to allow for alternative provision to come on-line.

Additionally regulated services

- 7.3 Although commissioners will have the lead responsibility for ensuring continuity of services, Monitor may also need to intervene to ensure continued access to key services in some limited circumstances. At present, Monitor has power to define ‘mandatory services’ obligations within the Terms of Authorisation for foundation trusts. Foundation trusts are not allowed to withdraw ‘mandatory services’ without Monitor’s permission. We propose to build on this approach in the new system, providing further protection, over and above that given by commissioners, to services that are vital to local populations. Under the proposed new approach, Monitor will be able to classify services which require additional regulation as additionally regulated

services and set conditions in providers' licences to protect the continuity of those services.

- 7.4 The purpose of defining additionally regulated services is to identify where it would be reasonable and proportionate for Monitor to impose additional regulation to support commissioners in maintaining access to essential public services. It will be for Monitor to set out the criteria for defining additional regulated services. These criteria are likely to focus on identifying where a provider is the only provider or one of very few providers of services in a local area. The justification for additional regulation in these circumstances is the need to maintain access to those services in the absence of alternative providers.
- 7.5 We envisage that Monitor would have powers to impose special licence conditions for providers delivering additionally regulated services, as an evolution of its current approach to regulating foundation trusts and taking a consistent approach irrespective of the type of provider. For example, we envisage Monitor having powers to impose special licence conditions to protect the assets needed to provide those services (such as controls on disposal of these assets). Special licence conditions could also include requirements on providers to give notice of planned changes to additionally regulated services. Providers would be obliged to continue to provide additionally regulated services during the notice period. This could be an extensive period, particularly if the services are difficult to replace. In addition, Monitor would be able to trigger application of a special administration regime to ensure the continuity of additionally regulated services and protect the assets used to deliver them in the event of insolvency.

Q18. Do you agree that Monitor needs powers to impose additional regulation to help commissioners maintain access to essential public services? If so, in what circumstances, and under what criteria, should it be able to exercise such powers?

Special Administration, insolvency and risk pooling

- 7.6 In certain areas of the economy, for example the water, transport and energy sectors, special administration arrangements have been put in place to ensure the continued supply of key services where a provider becomes insolvent. We propose to establish a similar special administration regime for additionally regulated health services in England. This will build additional protections, on top of those outlined above, to ensure the continued, safe provision of additionally regulated services in the exceptional event that a provider becomes insolvent. The special administration regime will work as in other

sectors, providing an alternative to ordinary insolvency procedures. It will build upon aspects of the unsustainable provider regime in the Health Act 2009, without some of the bureaucracy and ability for political interference. In the event of insolvency, Monitor will have 14 days to trigger special administration to protect additionally regulated services, before the start of any other insolvency process.

- 7.7 In these cases, a special administrator will be appointed with responsibility for securing the continued provision of additionally regulated services. The administrator will be required to develop plans to ensure the continuity of those services. Possible outcomes include transfer or rescue.
- 7.8 Monitor will be responsible for establishing funding arrangements to finance the continued provision of services in the event of special administration. It will have the freedom to decide on the best approach, which may change over time. However, it is likely that it will initially do this by establishing a ‘funding risk pool’, raised from levies on the providers of regulated services. These levies will be based both on the size of such providers and the level of risk that they may need to access the risk pool. Monitor will be responsible for determining an appropriate approach to risk assessment.

Q19. What may be the optimal approach for funding continued provision of services in the event of special administration?

8. Conclusion

- 8.1 This document supplements the White Paper, *Equity and excellence: Liberating the NHS*, by providing some further detail on freeing providers and economic regulation, and asking a number of specific questions. It does not attempt to be comprehensive in addressing all issues and the Department would welcome further comments and proposals. Following the introduction of the Health Bill later this year, we will undertake more work over the next two years to develop the detail of proposals, working with external organisations.
- Q20. Do you have any further comments or proposals on freeing foundation trusts and introducing a system of economic regulation?***
- Q21. What action needs to be taken to ensure that no-one is disadvantaged by the proposals, and how do you think they can promote equality of opportunity and outcome for all patients, the public, and where appropriate, staff?***
- 8.2 Our proposals for freeing providers and economic regulation form part of a coherent strategy for NHS reform. We are consulting on how best to implement these changes. In particular, the Department would welcome comments on the implementation of the proposals requiring primary legislation, and will publish a response to the views raised on the White Paper and the associated papers, prior to the introduction of the Bill.
- 8.3 The government has produced an analytical strategy for the White Paper and associated documents to expand and seek views on the detail behind key elements of the planned reforms. We will be issuing a full impact assessment on these proposals before publication of the Health Bill in the autumn.
- 8.4 Comments should be sent by 11 October 2010 to:
NHSWhitePaper@dh.gsi.gov.uk

8.5 This document seeks views on the following consultation questions:

- Q1. Do you agree that the Government should remove the cap on private income of foundation trusts? If not, why; and on what practical basis would such control operate?*
- Q2. Should statutory controls on borrowing by foundation trusts be retained or removed in the future?*
- Q3. Do you agree that foundation trusts should be able to change their constitution without the consent of Monitor?*
- Q4. What changes should be made to legislation to make it easier for foundation trusts to merge with or acquire another foundation trust or NHS trust? Should they also be able to de-merge?*
- Q5. What if any changes should be made to the NHS Act 2006 in relation to foundation trust governance?*
- Q6. Is there a continuing role for regulation to determine the form of the taxpayer's investment in foundation trusts and to protect this investment? If so, who should perform this role in future?*
- Q7. Do you have any additional comments or proposals in relation to increasing foundation trust freedoms?*
- Q8. Should there be exemptions to the requirement for providers of NHS services to be subject to the new licensing regime operated by Monitor, as economic regulator? If so, what circumstances or criteria would justify such exemptions?*
- Q9. Do you agree with the proposals set out in this document for Monitor's licensing role?*
- Q10. Under what circumstances should providers have the right to appeal against proposed licence modifications?*
- Q11. Do you agree that Monitor should fund its regulatory activities through fees? What if any constraints should be imposed on Monitor's ability to charge fees?*
- Q12. How should Monitor have regard to overall affordability constraints in*

regulating prices for NHS services?

Q13 Under what circumstances and on what grounds should the NHS Commissioning Board or providers be able to appeal regarding Monitor's pricing methodology?

Q14. How should Monitor and the Commissioning Board work together in developing the tariff? How can constructive behaviours be promoted?

Q15. Under what circumstances should Monitor be able to impose special licence conditions on individual providers to protect choice and competition?

Q16. What more should be done to support a level playing field for providers?

Q17. How should we implement these proposals to prevent anti-competitive behaviour by commissioners? Do you agree that additional legislation is needed as a basis for addressing anticompetitive conduct by commissioners and what would such legislation need to cover? What problems could arise? What alternative solutions would you prefer and why?

Q18. Do you agree that Monitor needs powers to impose additional regulation to help commissioners maintain access to essential public services? If so, in what circumstances, and under what criteria, should it be able to exercise such powers?

Q19. What may be the optimal approach for funding continued provision of services in the event of special administration?

Q20. Do you have any further comments or proposals on freeing foundation trusts and introducing a system of economic regulation?

Q21. What action needs to be taken to ensure that no-one is disadvantaged by the proposals, and how do you think they can promote equality of opportunity and outcome for all patients, the public, and where appropriate, staff?

Annex: The consultation process

Criteria for consultation

This consultation follows the ‘Government Code of Practice’, in particular we aim to:

- formally consult at a stage where there is scope to influence the policy outcome;
- consult for at least 12 weeks - the policies in this document were included in the NHS White Paper, *Liberating the NHS*, which was launched on 12 July for a 12 week consultation period closing on 5 October;
- be clear about the consultations process in the consultation documents, what is being proposed, the scope to influence and the expected costs and benefits of the proposals;
- ensure the consultation exercise is designed to be accessible to, and clearly targeted at, those people it is intended to reach;
- keep the burden of consultation to a minimum to ensure consultations are effective and to obtain consultees’ ‘buy-in’ to the process;
- analyse responses carefully and give clear feedback to participants following the consultation;
- ensure officials running consultations are guided in how to run an effective consultation exercise and share what they learn from the experience.

The full text of the Code of Practice and related guidance is on the Better Regulation website at www.bis.gov.uk/policies/better-regulation/consultation-guidance

Comments on the consultation process itself

If you have concerns or comments which you would like to make relating specifically to the consultation process itself please contact:

Consultations Coordinator

Department of Health

3E48, Quarry House

Leeds

LS2 7UE

e-mail: consultations.co-ordinator@dh.gsi.gov.uk

Please do not send consultation responses to this address.

Confidentiality of information

We manage the information you provide in response to this consultation in accordance with the Department of Health's Information Charter (available at www.dh.gov.uk).

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this, it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties.