Sector Regulation – a short guide to the Health and Social Care Bill

What you need to know as a provider of NHS services

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Policy	Clinical	Estates
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Document purpose	For information
Gateway reference	17282
Title	Sector Regulation – a short guide to the Health and Social Care Bill
Author	Department of Health, Sector Regulation
Publication date	23 February 2012
Target audience	NHS Trust CEs, Care Trust CEs, Foundation Trust CEs, NHS Trust Board Chairs, Allied Health Professionals, GPs, Communications Leads
Circulation list	
Description	This document outlines the Government's proposals to introduce a sector regulation regime which will apply to all NHS-funded health services (Part 3 of the Bill). It also gives an overview of planned legislative changes designed to increase autonomy and strengthen accountability for foundation trusts (Part 4 of the Bill).
Cross-reference	Protecting and Promoting Patients' Interests: the role of Sector Regulation
Superseded docs	N/A
Action required	N/A
Timing	N/A
Contact details	Zoe Lawrence Sector Regulation Room 229 Richmond House 79 Whitehall London SW1A 2NS 020 7210 2801
For recipient's use	

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Sector regulation

1. Summary

Subject to Parliamentary approval, the Health and Social Care Bill (the Bill) will establish a comprehensive, proportionate and robust legal framework for sector regulation to protect patients' interests. Its intention is to:

- focus clearly on protecting and promoting patients' interests;
- apply a comprehensive system of regulation for all types of provider;
- rationalise existing regulatory structures and reduce duplication; and
- create joint working between the Care Quality Commission (CQC), Monitor and the NHS Commissioning Board.

The Secretary of State for Health will retain overall accountability and powers to intervene where necessary.

Part 3 of the Bill will create a stable, independent regulatory regime on a statutory footing that will provide:

- independent pricing regulation, building on the current *Payment by Results* system;
- oversight of competition by a dedicated regulator with specialist knowledge and expertise of healthcare;
- a licence that will enable Monitor to set and enforce licence conditions to protect and promote patients' interests irrespective of who provides their NHS services (examples include gathering accurate cost data to set prices that will enable the delivery of high-quality care and to enable integration); and
- support commissioners to secure continuity of NHS services, where necessary.

2. Introduction

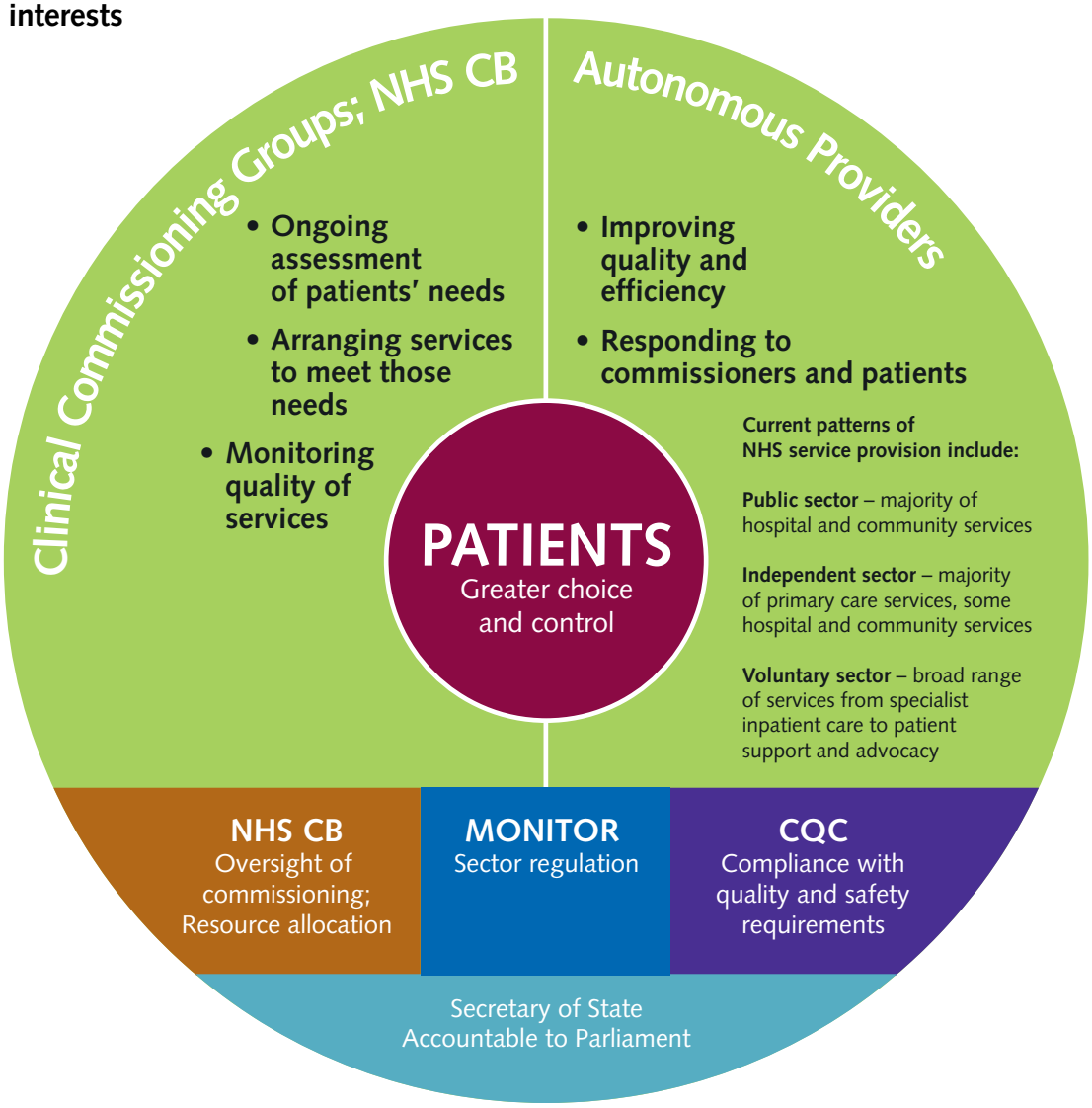
The Bill proposes to develop the role of Monitor – currently the independent regulator of foundation trusts – so that it will regulate all providers of NHS healthcare services in England. Monitor will continue to regulate foundation trusts while the remaining NHS trusts will be supported to achieve foundation status (or become part of a foundation trust) by 2014. This will mean that, for the first time, there will be a comprehensive system of healthcare regulation to protect patients' interests.

This document provides an overview of the Government's proposals for sector regulation in healthcare. It will apply to all NHS services – NHS trusts and foundation trusts, independent sector providers, charities and social enterprises. Further legislative changes designed to increase autonomy and strengthen accountability for foundation trusts are also planned.

2.1 Context

Initial policy proposals for sector regulation were outlined in the White Paper, *Equity and excellence: Liberating the NHS,*[1] and in the consultation document *Liberating the NHS: Regulating healthcare providers*[2] published in July 2010. These were further developed in response to consultation, as set out in *Liberating the NHS: Legislative framework and next steps*,[3] published in December 2010. Key changes were made to the proposals following a national 'listening exercise' to address the recommendations for improvement made by the NHS Future Forum. As part of the Parliamentary process, further changes have been made following the committee stage in the House of Lords.

Figure 1: A comprehensive framework for sector regulation to protect and promote patients' interests



Note: NHS CB = NHS Commissioning Board; CQC = Care Quality Commission

1 Department of Health (2010) *Equity and excellence: Liberating the NHS*. www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_117353
2 Department of Health (2010) *Liberating the NHS: Regulating healthcare providers*. www.dh.gov.uk/en/Consultations/Liveconsultations/DH_117782
3 Department of Health (2010) *Liberating the NHS: Legislative framework and next steps*. www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_122661

2.2 Liberating the NHS: the role of sector regulation

Our proposals aim to put patients at the centre of decision-making, empower clinical commissioners to lead in improving patient outcomes, and offer providers greater freedoms in return for greater accountability (**Figure 1**). A new comprehensive legal framework for sector regulation will be applicable to all those who provide NHS services and will be overseen by Monitor, building on its existing role as the regulator of foundation trusts. Monitor's role will be to promote patients' interests today and tomorrow by promoting value for money in the provision of healthcare services, while maintaining and driving improvements in quality.

NHS services will continue to be delivered by a 'mixed economy' of public, independent and voluntary sector providers, working within the values and principles enshrined in the NHS Constitution.[4] The Bill will not permit any discrimination in favour of private or other categories of provider. NHS services will continue to be free at the point of access, with access based on clinical need, not ability to pay.

With a growing population and people living longer, there is rising demand for health services alongside rising treatment costs. There are also variations in the quality of care across the country and a need for better integration of health and care services based on the needs of individuals. Therefore, it is critical that the NHS adapts and changes the way services are provided to ensure that it can continue to provide high-quality, efficient care to patients, when and where they need it.

Providers will have greater freedom *and* responsibility to respond to patient needs and to redesign their services to reflect priorities identified by GPs and other clinical commissioners. These priorities will be informed by engagement with local communities. To protect patients' interests, providers of NHS services will be required to adhere to essential standards and to comply with rules to ensure value for money for healthcare services, high-quality patient care and continuity of services, where needed.

Effective sector regulation in healthcare will play an important role in strengthening incentives for positive change, while protecting patients' interests, by ensuring essential standards and continuity of services, where necessary.

Patients must have confidence that they will continue to have access to essential services where there are no alternative providers, such as accident and emergency and critical care services. Access must be protected and provided at all times. Therefore, Monitor and clinical commissioners will have a responsibility to ensure continuity of services in the event of a provider getting into difficulty. Local clinical commissioners, in consultation with Health and Wellbeing Boards, will be responsible for ensuring continued access to healthcare services which meet the needs of local communities. Monitor's role will be to support commissioners in this through regulation designed to limit risk and ensure the availability of essential facilities (for example, buildings and equipment). Monitor will have power to intervene to ensure that these conditions are met and, as a last resort, to protect patients' interests by appointing an administrator to secure continuity of services in line with requirements determined by NHS commissioners.

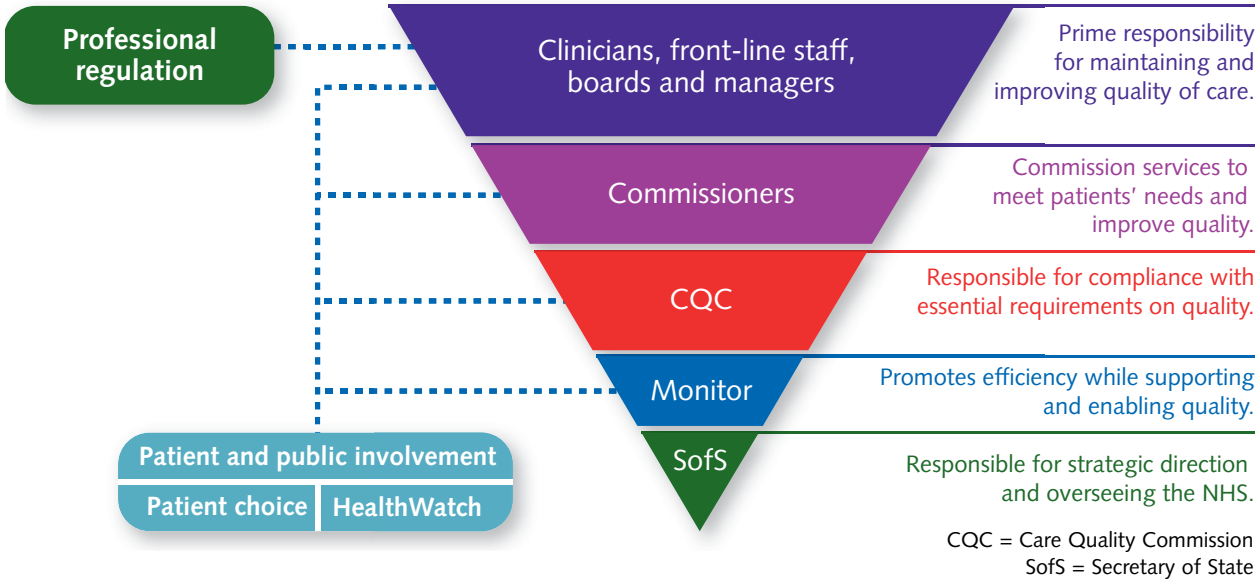
The proposals complement the roles of CQC, the NHS Commissioning Board and local clinical commissioning groups. Each organisation will

4 Department of Health (2010) *The NHS Constitution for England*. www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_113613

have distinct responsibilities; however, to carry out their duties effectively, they will need to work in partnership and cooperate effectively with each other. **Figure 2** illustrates this by setting out each organisation's respective responsibilities for quality.

The Secretary of State will oversee Monitor, CQC and the NHS Commissioning Board; will remain accountable to Parliament for delivering value for taxpayers' money; and will continue to have a duty to promote a comprehensive health service for patients in England.

Figure 2: Hierarchy of responsibilities for quality



3. Monitor's role and functions as sector regulator

Monitor's remit as sector regulator will cover all providers of NHS services. Its core functions are set out in **Figure 3** below.

Monitor's primary duty will be to protect and promote the interests of patients by promoting economy, efficiency and effectiveness in the provision of healthcare services, in the interests of patients, while maintaining or improving quality.

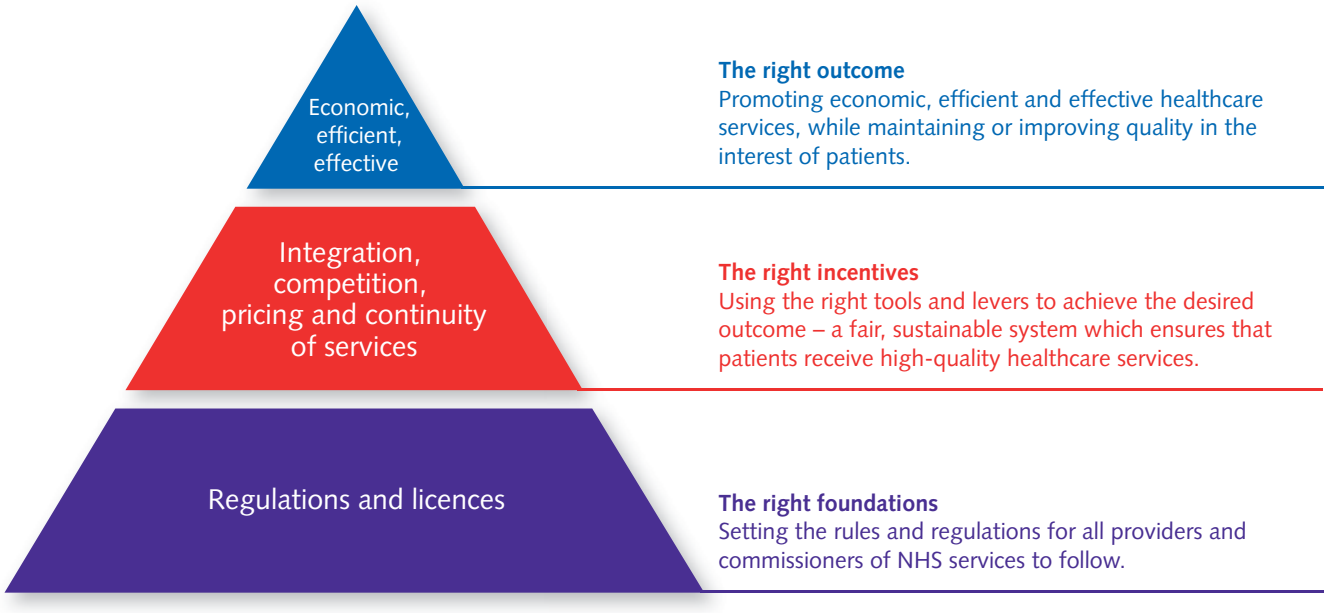
In addition, Monitor will have a duty to support commissioners by enabling the integration of services where this would improve quality or efficiency or help to reduce health inequalities.

It will carry out its duties through the following five key functions:

- licensing providers of NHS services and developing a joint licensing process with CQC to cover financial sustainability and clinical quality;
- 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 behaviour which acts against patients' interests; and
- working with commissioners to secure continuity of services, where necessary.

Monitor will determine the appropriate level of regulation that it considers necessary and proportionate for each provider. A minimum level of regulation will always be needed to protect patients' interests but the level that is set will vary in different circumstances.

Figure 3: Monitor's core functions as sector regulator



3.1 Licensing

Monitor, and CQC in due course, will operate a joint licensing regime, applicable to all providers of NHS services, unless granted an exemption under secondary legislation. Work is under way to develop policy on exemptions, and proposals will be published for consultation in early summer 2012. It is anticipated that the licensing regime will come into effect for foundation trusts in January 2013 and other providers from April 2013. Joint licensing will follow.

Monitor and CQC will work together to develop joint licensing so that once it is in place, providers seeking both CQC registration and a Monitor licence can complete a single application form and receive a single document confirming registration and a licence. Work is under way to develop this new mechanism. Existing providers who require a licence from 2013 but are already registered with CQC will be issued with a licence by Monitor. Re-registration with CQC will not be necessary.

Monitor will use the licence to:

- ensure minimum standards of governance and compliance with information requirements;
- set rules on cooperation to improve quality, support patient choice, enable integration and address anti-competitive behaviour that acts against patients' interests;
- ensure compliance with pricing regulations (including the national tariff); and
- secure continuity of NHS services.

To protect patient safety, it will be a prerequisite for every licensed provider to maintain the necessary registrations with CQC. CQC will retain independent powers to inspect providers and take action to ensure patient safety.

3.2 Regulating pricing

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

Pricing is an important lever for strengthening incentives for providers to develop and improve services in line with patients' and commissioners' priorities. The case for regulating prices for NHS services is strong. Many academics[5] agree that fixed prices will lead to competition on quality, not price, and that through this, the standard and quality of healthcare services will increase and patients' and taxpayers' interests will be protected.

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; and
- support movement towards a fairer playing field for providers.

To enable this, the Bill proposes to build upon and expand the previous Government's system of *Payment by Results*, which regulates pricing for NHS services through the national tariff and supplementary guidance.

Currently, the Department of Health sets the tariff. 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 can develop strong technical skills in setting prices at efficient levels.

The Bill proposes that Monitor will regulate prices working jointly with the NHS Commissioning Board. The NHS Commissioning Board will be responsible for specifying services (i.e. the currencies) which will be used as the basis of pricing and payments. The rationale behind this is that the NHS Commissioning Board is well placed to use its clinical expertise, knowledge and understanding of patients' needs to specify services that improve patient outcomes and service quality, as well as helping to ensure that the NHS is sustainable for the long term.

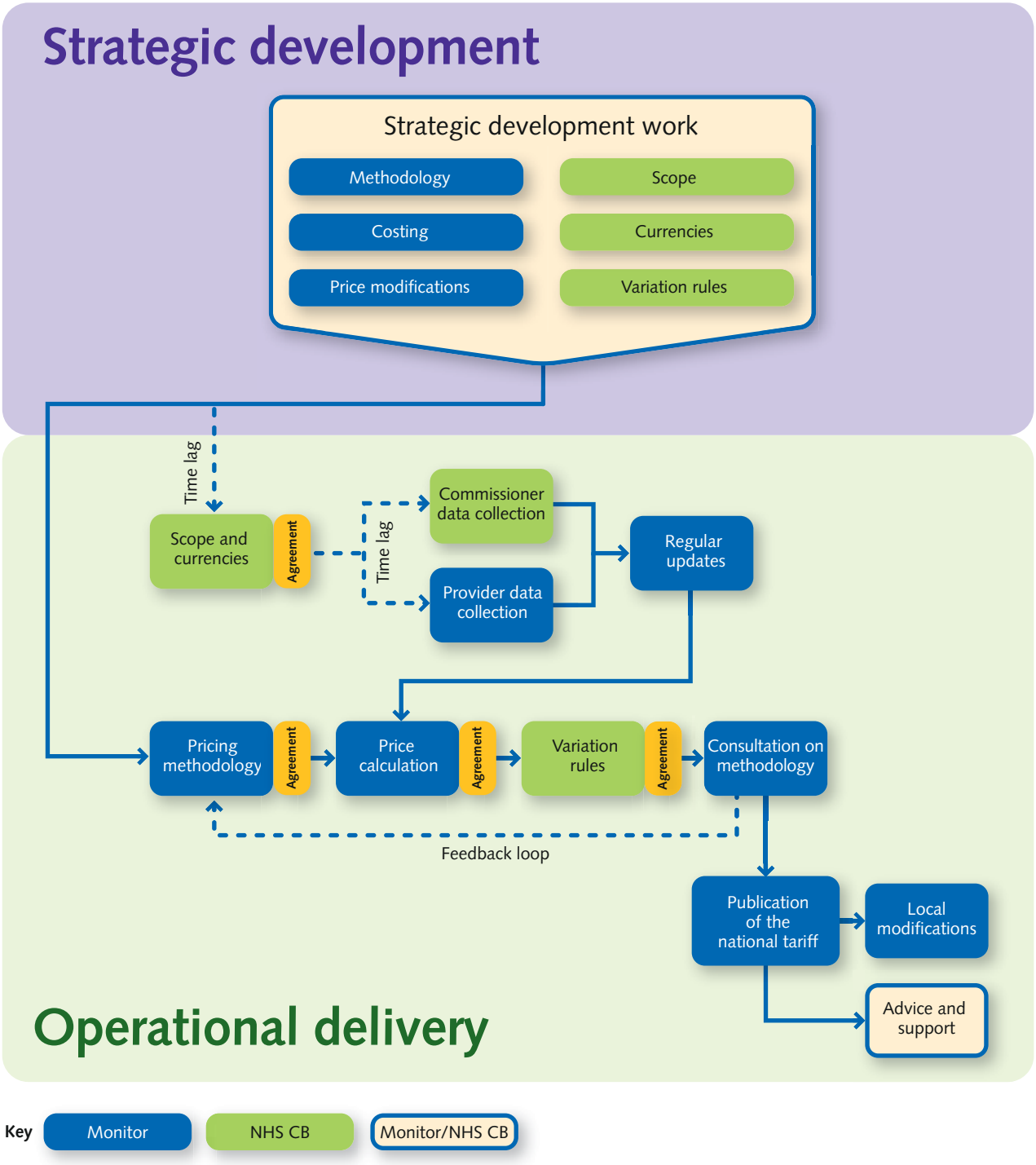
Monitor's role will be to develop the pricing methodology and calculate prices. This will ensure appropriate independence and objectivity in the pricing process, create the right incentives and ensure that prices reflect a robust understanding of provider costs.

At all stages, Monitor and the NHS Commissioning Board will have to agree the elements of the tariff with each other. The methodology will be subject to consultation and, if a sufficient proportion of providers object, it can be referred for independent review to ensure transparency and fairness. The prices and rules within the national tariff will be legally binding and independently enforceable on both providers and commissioners.

Figure 4 below sets out in more detail the anticipated process and the responsibilities of Monitor and the NHS Commissioning Board for tariff design and setting prices respectively.

5 Office of Health Economics Commission (2012) *Report of the Office of Health Economics Commission on Competition in the NHS*; 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 No.16164/CMPO Working Paper No.10/242. www.bris.ac.uk/cmpo/publications/papers/2010/wp242.pdf (covers the period 2003/04 to 2007/08); Cooper Z, Gibbons S, Jones S and McGuire A (2011) Does hospital competition save lives? Evidence from the English NHS patient choice reforms. *The Economic Journal* 121(554): F228–F260.

Figure 4: Anticipated high-level process for pricing, as set out in the Health and Social Care Bill



These reforms should enable progress towards meeting the efficiency savings required by the NHS while improving the quality of care for patients. Increasing the scope of the tariff, for example to cover community services, will make service reconfiguration away from acute settings easier. Improving the quality of data used to calculate prices can also improve their accuracy and support efficiency improvements. In addition, independent, transparent pricing would create a more stable, predictable environment, allowing providers and commissioners to invest in technology and innovative service models to improve patient care.

3.3 Enabling integration

Integration and choice are very important factors in delivering good healthcare services. Feedback from the NHS Future Forum and the Commission on Funding of Care and Support has shown that patients and healthcare professionals want more joined-up or integrated services. Evidence gathered from 16 Integrated Care Pilot sites, running since 2009, also supports this.

Integrated care pathways can enable increased collaboration between hospitals and healthcare professionals working in the community, between independent and public sector services, and between health and social care providers.

Commissioners will take the lead in promoting integration at a local level, enabling patients to have choice and control of their care. Every clinical commissioning group will have a statutory duty to promote integrated care, where this improves quality of patient care or reduces inequalities.

Monitor will have an overarching duty to enable integrated patient pathways of care and integrated services, where this will improve services or reduce inequalities for patients. The Government has recently tabled amendments to the Bill which would underpin this duty by creating powers for Monitor to set and enforce licence conditions for the purpose of enabling integration and cooperation in the provision of services.

3.4 Preventing anti-competitive behaviour

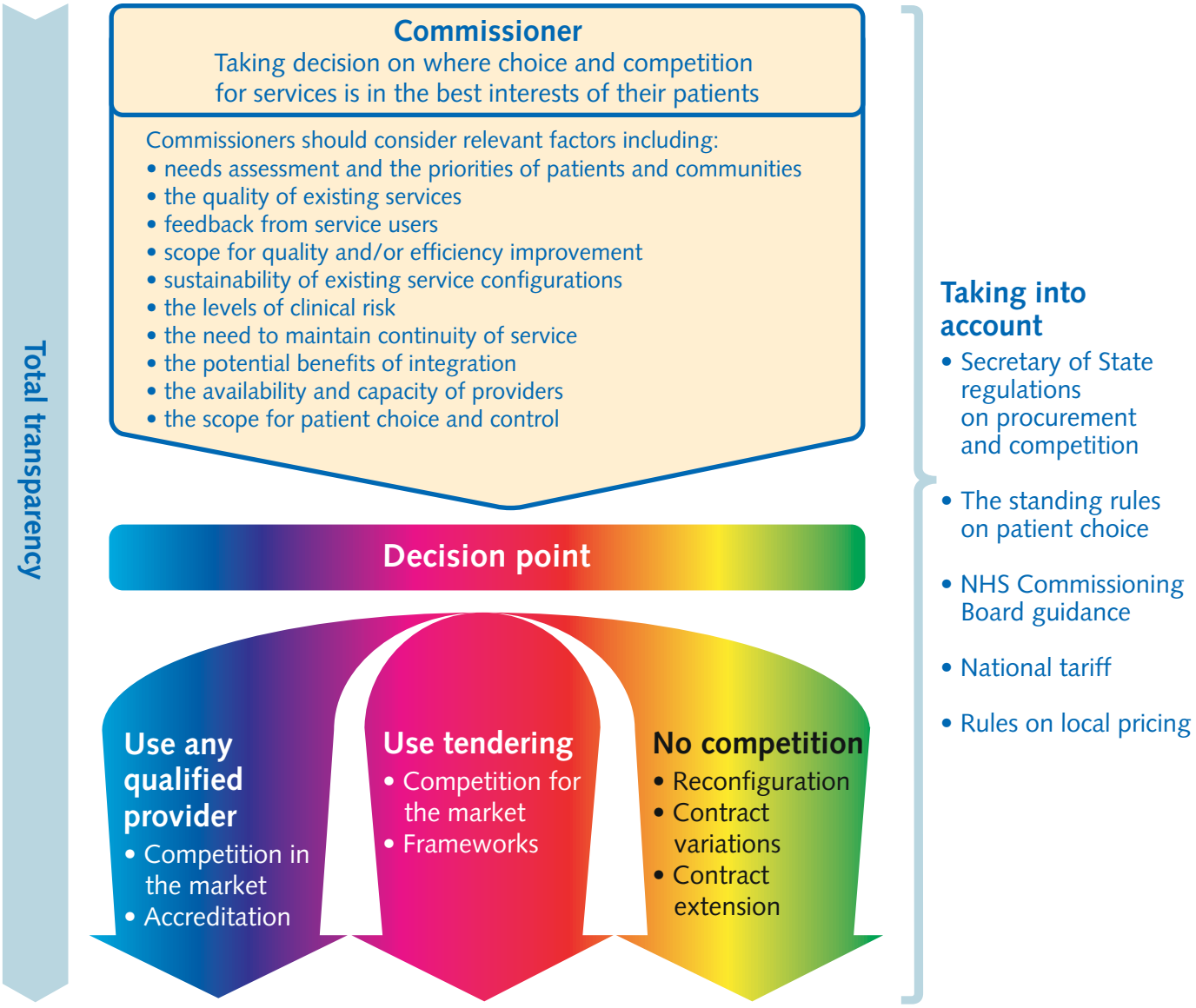
Clinical commissioners will decide when and how to use competition as a means of improving services within a framework of rules set by the Secretary of State and guidance from the NHS Commissioning Board to ensure transparency and value for money (**Figure 5**). Further information is set out in *Protecting and Promoting Patients' Interests: the role of Sector Regulation*.[6]

The overall aim is for NHS services to be commissioned from the best providers. This is consistent with the existing Principles and Rules for Cooperation and Competition (PRCC)[7] established by the previous Government.

The Government has committed that the PRCC will be reflected in a comprehensive set of sector-specific rules on procurement and competition which will be overseen by the sector regulator (**Figure 6**). Monitor's role will be to ensure that, where there is competition (as a result of decisions by commissioners), it operates effectively to protect patients, as well as addressing anti-competitive behaviour when it is not in patients' interests.

6 Department of Health (2010) *Protecting and Promoting Patients' Interests: the role of Sector Regulation*. www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_131609
7 Department of Health (2010) *Principles and rules for cooperation and competition*. www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_118221

Figure 5: Commissioners decide when and how to use competition



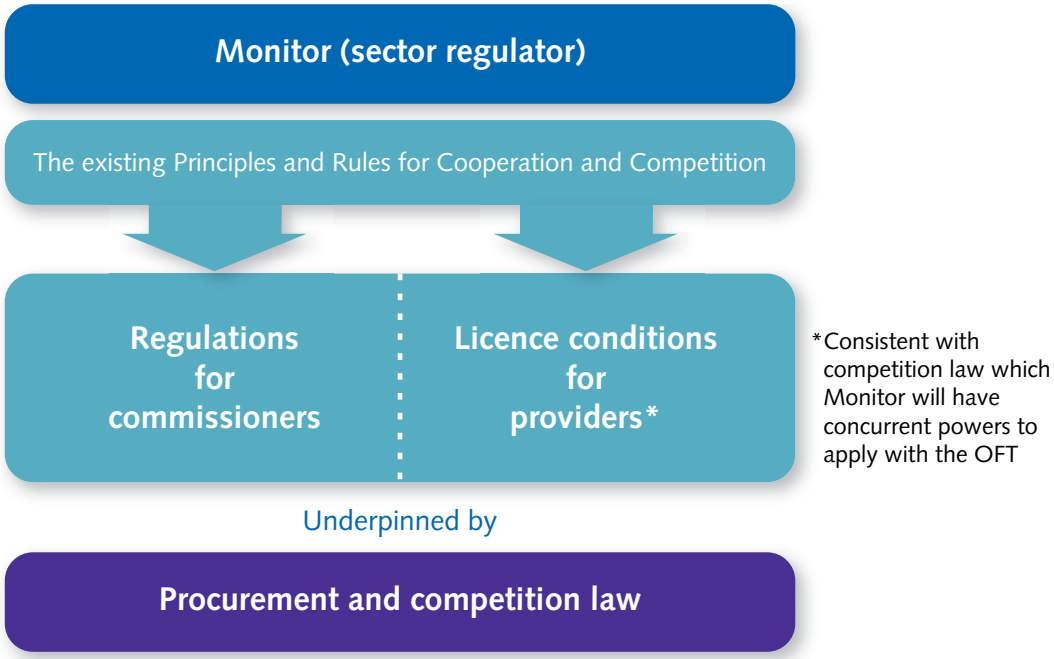
For providers of NHS services, Monitor will be able to set licence conditions to prevent conduct that undermines patient choice or restricts competition against patients' interests – these will also reflect the existing PRCC.

In addition, Monitor will have 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). Specifically the Competition Act restricts two kinds of anti-competitive behaviour:

1. Collusion – for example to restrict choice, limit output or quality, or fix prices.
2. Abuse of a dominant position – for example by unreasonably refusing to provide services.

Figure 6: Comprehensive, sector-specific rules on procurement and competition in healthcare, overseen by a sector regulator



The Bill will not extend competition law or its applicability to NHS services. Competition law would apply, where it applies, irrespective of the Bill. However, the Bill will help to ensure that competition law is only applied in the interests of patients.

As we have stated before, the OFT has confirmed that, when competition law is applied to a public body, functions or services of that public body will be considered individually. For example, therefore, competition law will not be applied across all of a foundation trust's operations or services. In this way, a foundation trust will likely be subject to competition law in relation to its privately funded services and where it is providing NHS services in competition with other providers. But, the same foundation trust will be very unlikely to be subject to competition law when providing a specific NHS service in the absence of competition and while under a licence obligation to maintain service continuity (for example accident and emergency, critical care, trauma, obstetrics). The Department of Health's correspondence with the OFT on this is published on its website (http://healthandcare.dh.gov.uk/competition-trusts/).

As a specialist health sector regulator, Monitor will be able to give expert guidance to providers and commissioners. Clinical commissioners would lead in deciding when, how or if to use competition as a means of improving services. In some cases competition may not be effective, for example where it would benefit patients for services to be provided through a clinical network (for example critical care or cancer care). We do not consider that such arrangements would be anti-competitive where they operate for the benefit of patients. Faced with a complaint, Monitor would be better placed than the OFT to identify these overriding benefits and avoid competition law being applied inappropriately.

3.5 Securing continuity of services

When a provider of NHS services becomes financially and/or clinically unsustainable, there must be a legal framework that provides effective safeguards to protect patients' and taxpayers' interests. However, the existing legal framework is not comprehensive and lacks an effective mechanism to improve poor-quality and inefficient services. The 'listening exercise' demonstrated widespread support for the principle of establishing a transparent framework: focused on securing patients' access to essential services and avoiding 'bailouts' for poor services at the taxpayer's expense.

Therefore, the Bill proposes an improved framework for securing continuity of NHS services, building on the current arrangements and extending these important safeguards to a broader range of providers. The improved framework will:

- protect patients' interests: patients must be able to get the services they need and those services must continue to be high quality – meeting the essential safety and quality registration requirements overseen by CQC and relevant clinical guidelines issued by the National Institute for Health and Clinical Excellence (NICE);
- ensure that health professionals take the lead: clinical commissioning groups will take the lead to secure continued access to essential NHS services, overseen by the NHS Commissioning Board. As part of their role, clinical commissioners – and the NHS Commissioning Board for directly commissioned services – should conduct a review of the sustainability of the services they commission. If any services are found to be underperforming in terms of quality and efficiency, commissioners should take proactive steps to address this;
- ensure that proactive action is taken: Monitor will support commissioners by regulating proactively to prevent providers taking actions that could significantly undermine their continued ability to deliver essential NHS services;
- provide an evolutionary approach: the previous Government's 'unsustainable provider' regime, established under the Health Act 2009, will be maintained and significantly improved. As part of this evolutionary approach, NHS trusts will continue to be governed by the existing provisions introduced by the Health Act 2009 until they achieve foundation trust status;
- make the clinical case for change: where services become unsustainable in their current form, proposed solutions will be driven by the clinical case for change, agreed by clinical commissioning groups and developed through consultation with the broader clinical community, local Health and Wellbeing Boards, Local HealthWatch and the public; and
- ensure that decisions are taken locally, not from the top down, and that democratic accountability is maintained: local authorities will have scrutiny of all service changes.

To ensure continued access to NHS services, swift action can be taken in a number of ways, including:

- the opportunity to modify the prices a provider is paid if they can prove that the prices they are being paid are not sufficient to reimburse the costs of the services it is required to provide, and can prove that this is not due to inefficiency;
- requiring a provider to appoint turnaround experts to help them when in financial difficulties; and

- ultimately, as a last resort, Monitor could appoint an administrator to take control of the provider's affairs and work with commissioners to secure continued access to essential services for patients.

Proactive regulation by Monitor will protect patients' interests by limiting risk and seeking to prevent failure until a solution is developed with commissioners. In particular, Monitor may impose controls over providers' decisions to dispose of essential facilities (for example, buildings and equipment) necessary for maintaining continuity of services, or it may impose requirements to maintain sufficient cash flow and avoid excessive borrowing so that, for example, the provider remains able to pay its staff and suppliers.

Furthermore, Monitor will have the power to levy providers and potentially commissioners to create a risk pool for providing financial assistance to providers in special administration to ensure patients have continued access to essential NHS services. The risk pool would also place important financial incentives on providers and commissioners to reduce the impact of any provider becoming unsustainable. Risk based levies would incentivise providers to take steps to mitigate their risk ratings, and commissioners could reduce their financial exposure by developing the market to introduce alternative providers, where possible.

These proposals will ensure a fair, transparent and comprehensive framework that protects both patients' and taxpayers' interests, by proactively supporting the continuity of services, while avoiding rewards for failure or 'bailouts' for poor quality and/or inefficient providers. CQC will continue to oversee providers' compliance with essential quality and patient safety requirements.

4. The impact of sector regulation on foundation trusts

NHS foundation trusts remain at the heart of the Government's modernisation plans and are some of the fittest trusts in the NHS.

All foundation trusts will remain as statutory bodies, via a local membership and council of governors. They have a unique legal form as public benefit corporations and their principal purpose, defined in statute, is to provide goods and services for the purposes of the NHS in England.

Governors – who are elected by and comprise of members of the public and NHS staff – and members, can enable foundation trusts to engage a powerful source of information so that boards know how to deliver more locally responsive care.

The greater freedoms for foundation trusts envisaged in the Bill, underpinned by a more comprehensive and robust system of sector regulation, will promote greater transparency and enhanced public scrutiny of foundation trusts, requiring stronger governance, making them more accountable to the populations they serve.

4.1 Monitor's continuing role in foundation trust regulation

Monitor will continue to regulate foundation trusts under the licensing regime envisaged in the Bill. This is currently planned to commence from January 2013, subject to the passage of legislation. Monitor will set licence conditions for foundation trusts and will have powers to intervene and direct foundation trusts to ensure compliance with those conditions.

Monitor will also have a specific transitional role in authorising NHS trusts applying for foundation trust status.

It will not be an option to remain an NHS trust, but the Bill does not specify a blanket deadline for NHS trusts to achieve foundation trust status. Nevertheless, the Government's expectation remains that most NHS trusts will achieve foundation trust status, as part of an existing foundation trust or in another organisational form by April 2014. A new special health authority, called the NHS Trust Development Authority (NTDA), will also be established to support NHS trusts to achieve foundation trust status. It will be established in shadow form in October 2012. From April 2013, it will assume full responsibility for supporting and delivering the foundation trust pipeline and performance management of NHS trusts, taking over this responsibility from strategic health authority clusters when they cease to exist.

The NTDA will work with NHS trusts to help them prepare to become foundation trusts and submit their applications to Monitor. The regulator will continue to assess foundation trust applications to its same rigorous standards until the pipeline has been delivered. Once all NHS trusts have achieved foundation trust status the NHS trust law will be repealed.

As part of the foundation trust application process, NHS trusts are required to demonstrate that they are clinically and financially sustainable. Under these proposals, Monitor will need to seek additional assurances from CQC that an individual trust is delivering care to the required CQC quality standard. This will give additional assurances to patients that their local trust is delivering high-quality and sustainable care.

Monitor's functions in authorising new foundation trusts will cease once all remaining NHS trusts have become foundation trusts (or have become part of foundation trusts). Legislative changes envisaged in the Bill will mean that a foundation trust could acquire another foundation trust or NHS trust without the need for both organisations to be dissolved. In addition, the Bill will make changes to improve the existing legislation so that unsustainable foundation trusts could be rescued as a going concern without the need to take the retrograde step of 'de-authorising' a foundation trust and removing its members and governors. (The effect of de-authorisation is that a trust ceases to be a foundation trust and reverts to being an NHS trust.)

The Bill also proposes that Monitor will have transitional powers to remove, suspend or disqualify one or more of its directors, or members of its council of governors, and appoint interim directors or members of the council. It is necessary to allow time to strengthen the capability of governors in holding foundation trust Boards to account, on behalf of their members (ie patients, staff and the wider public). Monitor will retain these powers until at least April 2016; or, for foundation trusts authorised after April 2014, for at least two years after the date of authorisation. The Secretary of State will have power to extend this transitional period by order.

It is not appropriate, however, for Monitor to retain power to remove, suspend or disqualify foundation trust directors, or members of its council of governors, in perpetuity. This would cut across the role of foundation trust governors. It would also hinder the Government's ambition to increase the ability of foundation trust Boards to transform NHS services for the benefit of

patients, by giving them greater autonomy in decision-making and to strengthen their accountability for the outcomes achieved. This could, therefore, risk putting foundation trusts at a disadvantage in relation to other providers. Moreover, retaining these powers in perpetuity would conflate the responsibilities of foundation trusts with those of Monitor because it would make Monitor ultimately accountable for the outcomes resulting from the decisions of foundation trust Boards.

Foundation trusts' principal purpose is to provide NHS services, and this means that the majority of their income must come from NHS sources. But they may earn income from other activities, and use the proceeds for the purposes of the foundation trust. Until now, foundation trusts have been subject to a cap on private patient income but under proposals outlined in the Bill this will be removed. This will enable these organisations to generate additional income, which will in turn benefit their provision of NHS services and support innovation within individual foundation trusts. Annually, each foundation trust must report all private activity and income to the council of governors and the members, to ensure that the trust continues to focus on delivering NHS services.

4.2 Strengthening foundation trust governance

To provide the highest quality services, trust boards need to have a strong strategic vision, have an in-depth understanding of their business and demonstrate robust financial control. Good governance is essential for high-performing organisations.

With strong governance in place, patients and the public can have confidence that their local trust board will be equipped to effectively and efficiently deal with future challenges and deliver high-quality health outcomes for their patients.

The NHS Future Forum recommended that there must be transparency on how public money is spent, and how and why decisions are made. As a result of these recommendations, foundation trusts must hold their trust board meetings in public, except in special circumstances to discuss confidential and sensitive matters.

Foundation trusts must continue to seek to ensure that their membership is representative of their community, and must take this into account when deciding upon their public and patient constituencies. Members can review the annual report and accounts, and vote on certain constitutional changes, if required.

4.2.1 Duty of governors

Governors are the crucial link between the foundation trust, its members and the population it serves. Foundation trust governors will be asked to take on additional governance responsibilities to make trusts even more accountable to their members and local community.

They will continue to have a duty to represent the interests of their members.

Under the current system, governors already have a duty to appoint a foundation trust's chair and non-executive directors and to approve the appointment of the chief executive. They can also already vote to remove the chair or a non-executive director from their post. These powers will be retained and strengthened further by giving governors new powers to hold non-executive directors to account for the Board's performance.

Any changes to a foundation trust's constitution or certain significant transactions, such as mergers, acquisitions and separations, will need approval by a majority of governors.

Governors will also be able to require directors to attend a special meeting to give information about their performance or that of their trust. At the meeting, governors can vote on a motion about the performance of the trust and its non-executive directors.

If governors have questions about whether their Board of directors is complying with the trust's constitution or with foundation trust legislation, Monitor may establish an independent panel to advise foundation trust governors on these issues.

The Department of Health will fund a package of training and support materials developed with input from expert partners and delivered through the NHS Leadership Academy. These materials will enable governors to develop the skills and knowledge they will need to fulfil their roles effectively, represent members' interests and hold directors to account.

4.2.2 Duty of directors

Directors will have a new duty to ensure that they promote the success of their foundation trust and operate their organisation in a way that reflects the interests of the members of the trust they serve. They will also have a duty to ensure that governors are equipped and have the support they need to perform their roles effectively.

Directors will have a duty to avoid conflicts of interest.

Directors must publish remuneration reports, as part of their annual report, outlining salaries paid to directors, as well as expenses paid to both directors and governors.

5. What sector regulation means for independent and voluntary sector providers

The Bill will establish a comprehensive system of sector regulation which will be applicable to all providers of NHS healthcare services. This is necessary to ensure that there are appropriate safeguards to protect patients' interests, irrespective of who provides their NHS services, and to address key weaknesses of the current system. These weaknesses have, for example:

- resulted in insufficient regulation of service sectors that depend heavily on independent providers (for example mental health);
- enabled previous governments to exclude NHS organisations from bidding for new contracts;
- allowed some providers to make excessive profits from routine procedures; and
- failed to address barriers to increasing patient choice and supporting competition, where appropriate, on a fair playing field.

A more comprehensive system of sector regulation will help to address these problems, for example by bringing independent and voluntary providers within the scope of the new licensing regime and Monitor's powers to regulate prices. The Bill will also require Monitor to avoid imposing excessive regulatory burdens. Monitor will have clear duties to ensure that regulation is targeted and proportionate, and to keep this under review. This is necessary to avoid increasing costs or stifling innovation in ways that would not be in patients' interests, and for supporting a fair playing field for providers.

For example, Monitor will only impose additional regulation on independent and voluntary providers to secure continuity of services where this is necessary and proportionate, to support

commissioners in securing continued access to those services, and where transferring patients to alternative providers is not an option.

In addition, the Bill envisages that some providers will be granted exemptions from the licensing regime under secondary legislation. The Department of Health plans to consult on its exemptions policy in early summer 2012. Exemptions will help to ensure that sector regulation is targeted appropriately and is proportionate (i.e. costs must be outweighed by benefits). Exemptions could be determined for individual providers or groups of providers. Key considerations for the Department of Health in determining exemptions will include identifying: *de minimis* criteria for exempting smaller providers; categories of providers that operate in service sectors where it may not be cost-beneficial to impose additional regulation; and potential exceptions to these general exemptions in individual cases (for example in particular geographies or for particularly powerful providers).

6. Share your views and get involved – planned consultations

Subject to the passage of the Bill through Parliament, the Department of Health plans to engage and involve stakeholders on the development of regulations to further support Monitor's functions. Consultation documents will be made available to our key partners and stakeholders, as well as being published on the Department of Health website. Each consultation will be an opportunity for health and social care organisations to share their views on particular aspects of the regulations.

Proposed consultation date	Policy area
April–June 2012	Licensing – regulations to clarify who is the licence holder and exemptions from the requirement to hold a licence; regulations to prescribe a threshold for referring disputed licence modifications to the Competition Commission; and regulations to define turnover for variable monetary penalty. Risk pool – regulations to specify a threshold for referring disputed levies on providers to pay into the risk pool to the Competition Commission. Pricing – regulations to specify a threshold for referring disputed pricing methodologies to the Competition Commission; and regulations to define 'relevant providers'.
July–September 2012	Regulations for NHS commissioners – for the NHS Commissioning Board and clinical commissioning groups to adhere to good procurement practice, protecting patient choice, and to prevent anti-competitive behaviour. Regulations for commissioner charges to the risk pool.
May–July 2012	Health Special Administration Regulations – to make further provisions about health special administration orders for companies.

7. Proposed timetable for implementation

Function	Implementation milestone	Date
General	Monitor's overarching duties and general powers begin. Most foundation trust new duties begin (apart from those linked to licensing).	July 2012
Licensing	Licensing for foundation trusts plus related foundation trust duties begin.	January 2013
	Licensing regime for all providers begins.	From April 2013
	Regulations (including exemption) to support the provider licensing regime come into force.	April 2013
Competition	Competition Act 1998 powers concurrent with OFT are commenced.	January 2013
	Regulations for NHS commissioners protecting patient choice, procurement, and preventing anti-competitive behaviour come into force.	April 2013
Pricing	Monitor commences pricing functions with the NHS Commissioning Board for 2014/15 tariff.	From July 2012
	Regulations to specify threshold for referring disputes to the pricing methodology to the Competition Commission come into force.	April 2013
Continuity of services	Foundation trust continuity of service regime (this is dependent on the licence) commences.	January 2013
	Regulations to specify threshold for referring disputes to provider levies to the Competition Commission and commissioner charges regulations come into force.	April 2013
	Financial mechanisms (risk pool) go live.	April 2014
	Health special administration (companies), including regulations and rules, comes into force.	April 2014

408836 1p 0K Feb 2012
Produced by COI for the Department of Health

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