Key Points

- The creation of Monitor as an economic sector regulator is central to achieving the government's vision of a 'liberated' NHS. The Health and Social Care Act 2012 allows Monitor to enforce rules, such as providing good quality data on pricing, prohibiting anti-competitive behaviour, and supporting patient choice, continuity of service and integrated care, as appropriate.
- Assessing the scope and content of the licence is hampered by the still incomplete level of detail about how, precisely, Monitor will function in relation to many of its duties for instance the requirement to provide information. In other areas, government policy is not fully developed, for example in relation to patient choice.
- We are concerned about the relative weight being placed on developing sector regulation licensing (carried out by Monitor and other organisations) relative to developing and improving quality regulation, carried out by the CQC for providers and the NHS CB for commissioners. Indeed, the precise regulatory role of Monitor with respect to quality of care is unclear.
- Viewed from a perspective of public legitimacy (this includes patients, the public and those working in the NHS), there is a risk that the new regulatory architecture will be seen as diverting energy and resources in the wrong direction.
- It will be critical for the Department of Health/Secretary of State to regularly review how the roles of Monitor, the NHS CB and the CQC are developing individually, and more importantly together, in the development of the NHS to achieve high-quality and efficient care for all.

Consultation response Date 23 October 2012 We are pleased to be able to respond to Monitor's consultation on the draft licence for providers of NHS services. The Nuffield Trust is an authoritative and independent source of evidence-based health service research and policy analysis. Our aims include promoting informed debate on health care policy in the UK. Below, we offer some brief overall comments and answers to some of the specific questions posed by the consultation document.

Overall comments

The creation of Monitor as an economic sector regulator is central to achieving the government's vision of a 'liberated' NHS. According to this vision, the quality and efficiency of services will be shaped by clinically-led local commissioners, supported by the extension of market forces (enhanced patient choice and competition) and more robust pricing mechanisms, alongside traditional tools, such as quality regulation and inspection, centrally-provided guidance on clinical standards and support for improvement.

Through the instrument of the licence, the Act allows Monitor to enforce rules, such as providing good quality data on pricing, prohibiting anti-competitive behaviour, and supporting patient choice, continuity of service and integrated care, as appropriate. It is crucial that Monitor functions in a coordinated way with the regulators who shape the behaviour and performance of staff delivering NHS services, particularly the CQC and the NHS CB.

Assessing the scope and content of the licence is hampered by the still incomplete level of detail about how, precisely, Monitor will function in relation to many of its duties for instance, the requirement to provide information (how much information, or of what type¹). In other areas, government policy is not fully developed, for example in relation to patient choice (for example, will patients have rights to choice of provider or treatment at all points in the patient pathway?).

In those areas where detail is emerging, for instance in the draft guidance on commissioner requested services and the failure regime, Monitor's scope is potentially large and its ability to intervene and shape local services is extensive.

Given the incomplete nature of the detail about how Monitor will function, it is hard to assess the full implications of many of the draft licence conditions, in terms of their impact on individual providers, commissioners and the health system as a whole. One of the unresolved issues arising from the negotiations preceding the passage of the Act is the appropriate scope for the role of competition, relative to other mechanisms available to policy-makers and commissioners in the NHS. It remains the case that the evidence base in favour of competition and choice in the NHS is incomplete. The vast bulk of the evidence that supports the benefits of provider-based competition comes from the US, where for historical reasons there is very limited scope for state or federal

¹ For example, the impact assessment states (in relation to information): "Monitor has not yet, however, formulated its plans on what actions it may require licensees to perform under this licence condition, specifically what and how much information Monitor may require licensees to publish and these plans are, in any event, likely to change over time to reflect changing needs and circumstances." Impact Assessment - the new NHS provider licence, final report. September 2012. Monitor. http://www.monitor-

governments to influence the behaviour of providers, who operate in a market-based system. Powerful sector regulation is therefore essential to ensure that competition is preserved, as one of the key mechanisms to contain costs.

The same does not apply in the NHS: the widely-cited evidence to date (of the patient choice policy from 2006) applies to a narrow slice of the hospital sector. While the apparent effect of competition on clinical quality looks strong, the explanatory mechanisms are missing. We do not have a clear understanding of how competition affects the culture of NHS organisations, or the behaviour and motivations of individual managers and clinicians in the NHS relative to other methods of improving quality and efficiency (similarly, the evidence base on integration is equally, if not more, under-developed: Monitor and other organisations have a vital role to play in building the evidence base in the future).

Many of the ideas being developed in and on behalf of Monitor derive from other sectors of the economy. But the information asymmetries in many forms of health care are more complex and profound than for many other equivalent sectors where sector regulation has been set up following privatisation. Some have argued that competition (driven either by consumers or through commissioner contracts) will be best suited to a limited range of health services which have discrete episodes and unambiguous quality metrics, to enable either patient choice or commissioner-led contracting (Office of Health Economics, 2012).

As a result of this, it is important that the regulatory functions of Monitor are balanced with the approaches and functions of other regulators and relevant organisations. The new regulatory world created by the Health and Social Care Act envisages a mixture of approaches from different bodies, including the CQC, the NHS CB and Monitor. It is not yet clear which approach will be dominant. In the short run, while Monitor (and parallel organisations) are still establishing themselves, sector (i.e. economic) regulation is likely to be underpowered, because the staff, information, guidance and monitoring systems are not yet in place and may take years to mature. This embryonic state should not obscure the future trajectory of economic regulation, which could potentially be very powerful and will interact with other system reform levers – particularly quality regulation, commissioning and design of payment currencies by the NHS CB, in ways which are not yet clear.

We are concerned about the relative weight being placed on developing sector regulation licensing (carried out by Monitor and other organisations) relative to developing and improving quality regulation, carried out by the CQC for providers and the NHS CB for commissioners. Indeed, the precise regulatory role of Monitor with respect to quality of care is unclear.

Viewed from a perspective of public legitimacy (this includes patients, the public and those working in the NHS), there is a risk that the new regulatory architecture will be seen as diverting energy and resources in the wrong direction. The public are concerned about the clinical quality of care, especially as resources tighten in the NHS amidst growing demand for services. There is considerable scepticism about the potential for competition/new entrants to either preserve or improve quality improvements on the scale needed in the NHS, compared with other mechanisms.

It will be critical for the Department of Health/Secretary of State to regularly review how the roles of Monitor, the NHS CB and the CQC are developing individually, and more

importantly together, in the development of the NHS to achieve high-quality and efficient care for all. The roles of these bodies are intertwined, and more effective collaboration than in the past will be critical as the NHS faces the very tough next decade given funding constraints. Effective coordination with respect to the national strategies will thus be key, and the mechanisms the DH and the Secretary of State will put in place to hold all three organisations to account for this are not clear. Furthermore, effective coordination at a local level is equally important and should be regularly assessed so that the burden and impact of sector regulation on local providers and commissioners is appropriate.

Responses to specific points raised in the consultation

General licence conditions

1) Fit and proper persons (Chapter 1, Q1 and Q2)

Exceptions: we think that these will be rare, but should be allowed if there is a clear rationale, i.e. that an individual bringing a unique service user perspective will be important on a governing body. More substantively, from a public and patient standpoint, a requirement for governors and directors to adhere to standards is a reasonable suggestion, and would counter the concerns in some quarters that sector regulation is doing no more than applying essentially business standards from other sectors. Our concern relates to the feasibility of Monitor to enforce a standard with a broader scope in any meaningful way, beyond its direct role with foundation trusts. How would patients and the public voice concerns about the integrity of boards or individuals who sat on them? How would Monitor investigate these? Should this be Monitor's role?

2) Systems for compliance with licence conditions (Chapter 4, Q1)

We agree that it would be sensible for Monitor to avoid being over-prescriptive in how organisations should demonstrate that they have systems for compliance. Nevertheless, with option B (which relies on appropriate systems and self-certification) it would still be important to know how Monitor intends to validate organisations' accounts of their actions.²

3) Effectiveness, efficiency and economy (Chapter 4, Q2)

It would seem reasonable to remove this requirement. It is arguably the duty of commissioners to drive this, and it is odd to separate these values from service quality. However, the removal of this requirement and the suggested re-wording of the integration requirement (see below) might have the effect of raising the relative importance of the licence requirements on competitive conduct and patient choice, which, as we have pointed out above, is only one route to improved quality and efficiency.

4) Pricing licence conditions – recording of information

Although the consultation does not pose a specific question about information gathering to support accurate pricing, given the strength of the evidence for the need to have accurate cost information to underpin pricing (and as a foundation for efficiency within organisations) (Bardsley and Blunt 2012), we suggest that the NHS CB, Monitor and

² An example would be the experience of NHS organisations' compliance with legislation, such as the Race Relations Amendment Act: despite ample documentation and appointment of relevant staff, many organisations were taking very little action to reduce inequalities in access to care (Thorlby and Curry, 2007; Healthcare Commission, 2009).

others jointly agree and publish a core set of requirements for data collection, exchange and publication for accountability. The licence should require bodies to comply with this. We would also encourage Monitor (and other relevant bodies) to ensure that there are adequate sources of support for providers – of all sizes and ownership models – to achieve this, particularly smaller providers or those in the voluntary sector. It will also be important for Monitor to consider how best to address the lack of information, data and transparency on the pricing of non-tariff activity. This represents is a very substantial block of acute and community work. It will be important that Monitor places as much focus on improving the rigour of the pricing system here as for the tariffs which underpin Payment by Results.

5) Choice: the right of patients to make choices. (Chapter 6, Q1)

The difficulty with this condition is the confusion between choice as a dimension of clinical quality – demonstrably important for patients – and as a specific policy instrument to inject more competition into the NHS (choice of hospital provider for non-urgent care and, more recently, the 'any qualified provider' policy for a range of community services).

It is not clear which of these the licence is intending to support. If it is the general principle of choice, there is an immediate question about enforcement. In general, the exercise of choice by patients is not monitored: how does Monitor propose to establish whether providers are offering patients choices as appropriate? Choices are potentially available at multiple points along a patient pathway, within providers and between providers, however, these choices are not enshrined in the NHS Constitution.

As for the specific question about whether there should be an additional requirement for impartial advice where a provider offers further choices to patients, there is clearly some merit in this, at a theoretical level. In practice, given the current choice policy at the point of GP referral, the burden of this will fall on GPs, especially those who also provide services themselves. Under the current proposals about the scope of licensing, individual GP practices, or small consortia of practices, are likely to be too small scale to meet the proposed threshold for licence holding, and enforcement duty will in any case fall to the NHS CB. Clarification is needed on this point.

6) Competition oversight

The consultation document makes clear that the competition licence condition extends the reach of the Competition Act 1998 to a wider range of providers, and fills the 'potential enforcement gap' as it applies to all licensees. Given the scepticism about the potential of competition to undermine collaboration that surfaced in the debates prior to the Act, it is vital that Monitor publishes guidance, with practical examples, to explain to providers what conduct is and isn't acceptable. This is particularly important in relation to the duties to deliver more integrated care.

The experience of the Netherlands and the US (in relation to the Medicare Shared Savings Accountable Care program) is instructive here. Both regulators have published detailed guidance to explain what is and is not permissible under competition law (Nederlandse Mededingautoriteit, 2010; US Federal Trade Commission/Department of Justice, 2011). Without this, there is a danger that providers will not collaborate or innovate for fear of breaching competition rules.

7) Integrated care licence condition (Chapter 7, Q1)

The impact assessment makes it clear that the duty contained in the legislation – to integrate care when in the best interest of patients – is likely to be more relevant to commissioners (and the NHS CB) and that the integrated care licence condition will only be applicable in 'rare' instances(Impact assessment, p64). This, coupled with the weak evidence base underpinning integration, has led Monitor to suggest a double negative licence condition, i.e. the 'licensee shall not do anything that would reasonably be regarded as detrimental to enabling integrated care'.

While we understand the logic behind this suggestion, the spirit of the integrated care duty (added as a result of revisions to the bill) was that it should act as a counterweight to the emphasis on competition. It is difficult to see how this licence condition will carry much weight phrased in this way, especially given the inability of commissioners or regulators to assess the extent to which care is currently fragmented and in need of integration.

8) Continuity of service licence conditions

Developing an adequate failure regime for NHS-funded services is an important and overdue task, which has been hampered in the past by concerns that patients will suffer if services are allowed to 'fail'.

Monitor's proposed continuity of service regime is a welcome attempt to apply a systematic and transparent process to identify essential services and protect them in the event of failure. However, we have a few concerns about how it will operate in practice.

It is not clear whether this is an essentially top down or bottom up process. Although it is described as 'commissioner requested services (CRS)', in the first instance, these will initially apply only to the mandated services provided by foundation trusts. In this consultation document, Monitor makes it clear that it wishes to see these essential services gradually redefined by commissioners, and perhaps reduced in scope, while including providers from the independent and third sectors. Monitor recognises that the increased scrutiny and control over changes to services that accompanies the CRS status 'may deter new provision by alternative providers and new investment in CRS' (p47 paragraph 2). In other words, there is a risk that a widely-defined set of CRS could inadvertently have the effect of freezing the reconfiguration of local services in some areas.

The accompanying draft guidance on the designation process sets out a very technical process, including market studies of every local service for commissioners to follow. This represents a significant future cost for commissioners in terms of skills and capacity to deliver such a rigorous process for identifying designated services. In addition to the challenges posed by this, more thought might need to be given to the role of local government and local communities in this process. In the current climate, it is possible that CRS will be seen by some as a way of protecting services from reconfiguration or avoiding competition; potentially setting commissioners and local communities at loggerheads. Will Monitor be stipulating that commissioners must have consulted and reached some degree of consensus locally? What happens in the event of local commissioning groups disagreeing with each other? If Monitor is required to approve any changes to CRS conditions, will this decision be subject to any local scrutiny?

Risk pool levy

We understand that a separate consultation will take place next year on the details of how a risk pool levy should be set and who should be required to contribute, including commissioners. Including contributions from commissioners will be a potentially useful tool to discourage an overly broad scope of local CRS services. But setting an appropriate rate will be a sensitive task; balancing demands on limited management budgets against the risk of setting levels too low to be meaningful. Similar considerations will need to be applied to providers.

In the event that a provider of CRS services from the independent sector gets into financial difficulties, can Monitor clarify whether public funds will flow to sustain their services? Will independent sector providers who get into difficulty also be subject to the same level of financial scrutiny as publicly-owned organisations?

References

Bardsley M and Blunt I (2012) Patient-level Costing: Can it Yield Efficiency Savings? Nuffield Trust. <u>http://www.nuffieldtrust.org.uk/publications/patient-level-costing-can-</u> <u>it-yield-efficiency-savings</u>

Department of Health (2011) NHS Future Forum Summary Report on Proposed Changes to the NHS.

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/documents/documents/documents/documents/documents/documents/documents/documents/documents/documents/documents/documents/documents/documents/documents/do

Healthcare Commission (2009) Tackling the Challenge: Promoting Race Equality in the NHS in England.

http://archive.cqc.org.uk/ db/ documents/Tackling the challenge Promoting race e quality in the NHS in England.pdf

Nederlandse Mededingautoriteit (2010) *Richtsnoeren Zorggroepen* (Netherlands Competition Authority: *Guidelines for Care Groups*). http://www.nza.nl/104107/136998/Richtsnoeren Zorggroepen.pdf

Office of Health Economics (2012) Report of the Office of Health Economics Commission on Competition in the NHS. <u>http://www.ohe.org/publications/article/report-of-the-ohe-commission-on-competition-in-the-nhs-108.cfm</u>

Thorlby R and Curry N (2007) *PCTs and Race Equality Schemes*. King's Fund http://www.raceforhealth.org/storage/files/resources/PCTsRaceEquality_1_.pdf

US Federal Trade Commission/Department of Justice (2011) Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program. <u>http://www.justice.gov/atr/public/health_care/276458.pdf</u> For more information about Nuffield Trust, including details of our latest research and analysis, please visit www.nuffieldtrust.org.uk

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