**Protecting and promoting patients' interests – licensing providers of NHS services**

**A consultation response from the Nuffield Trust**

22nd October, 2012

We are pleased to be able to respond to the Department of Health's consultation on licensing providers of NHS service. 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 healthcare 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 on licencing*.**

One of the primary objectives of the Health and Social Care Act was to increase the autonomy of NHS providers and commissioners by reducing the dominance of centrally driven targets, planning and performance management. In its place, the architects of the reform intended that the quality and efficiency of services would 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 and innovation.

The creation of Monitor as an economic sector regulator is central to achieving the government's vision of a 'liberated' NHS. 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, supporting patient choice, continuity of service, and integrated care as appropriate. We are responding separately to Monitor's consultation on licensing.

The draft licence and accompanying impact assessment makes clear that there is still uncertainty 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 type[1]) or the obligation on providers to help patients make choices (choice at all points in patients' treatment trajectories?) . Given the incomplete nature of Monitor's functioning, it is hard to assess the likelihood of the ambition, stated in para 10 (p9) of this consultation, that effective sector regulation as a whole depends on a 'set of rules that are applied and enforced consistently across all providers'.

[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-nhsft.gov.uk/sites/default/files/Final%20report%20IA.pdf

The new regulatory world created by the Health and Social Care Act, envisages a mixture of approaches from different bodies, including the CQC, Commissioning Board 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 (ie 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 the economic regulation, which could be potentially very powerful and will interact with other system reform levers- particularly quality regulation, commissioning and design of payment currencies by the Commissioning Board, in ways which are not yet clear.

We are therefore concerned about the relative weight being placed on sector regulation licensing (carried out by Monitor and other organizations) relative to quality regulation, carried out by the CQC for providers and the NHSCB 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, public and those working in the NHS), there is a risk that the new regulatory architecture will be seen as directing energy and resources in the wrong direction. The public are (arguably) most concerned about the clinical quality of care, especially as resources tighten in the NHS amidst growing demand for services. There is considerable uncertainty 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 review regularly 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 Secretary of State will put in place to hold all three organisations to account for this are not clear. Furthermore effective coordination at local level is equally important and should be assessed regularly so that the burden and impact of sector regulation on local providers and commissioners is appropriate. This scrutiny by DH/Secretary of State should perhaps be carried out before the scheduled time, (ie perhaps before 'the next Parliament').

***Question 1: Do you think NHS trusts should be exempt from the requirement to hold a licence, but expected to meet equivalent requirements to those in the general, pricing (where appropriate), choice and competition and integrated care sectors of Monitor's licence, overseen by the NHS Trust Development Authority?***

The logic behind this suggestion (that trusts should be exempt from holding a licence) rests on the assumption that an alternative body- in this case the NHSTDA- is well placed to enforce the same requirements that Monitor will be requiring in licence. It may also be based on pragmatic reasoning, namely that in the short term Monitor is expected to licence around a 1,000 organisations which will represent a considerable administrative burden for a fledgling regulator. Overall, we welcome this

approach, as it is important that regulatory bodies do not duplicate each others' work. If the NHSTDA already has a strong performance management role in relation to NHS trusts, supervision of the dimensions specified in the licence seems reasonable, in theory.How well this will work in practice will, however, depend on the clarity of the- as yet unpublished- guidance and modus operandi to be used by Monitor, for example about how it will ensure that the relevant licence conditions are being met. As we have pointed out elsewhere, for example in relation to patient choice and integration, there is a dearth of monitoring to indicate whether choice is being offered in a meaningful way or the extent to which patients are experiencing fragmented, uncoordinated care. It also will be vital that NHS trusts are encouraged and supported to collect robust costing data. If these monitoring and surveillance systems are not adequately clarified and codified, so that other organizations can easily replicate them, it will create a temporary imbalance in the system, particularly if Monitor's directly licensed organizations are subject to a more rigorous surveillance regime.

**[Questions 3-6 taken together]**
***Question 3: Do you agree that it is not appropriate to license small and micro providers of NHS funded services, at this stage, pending further review of costs and benefits?***
***Question 4: If so, do you agree that providers of NHS services with fewer than 50 employees (FTEs) and income from the provision of NHS hospital and community healthcare services of less than £10 million should be exempt from the requirement to hold a licence?***
***Question 5: Alternatively, do you think a de minimis threshold based on a provider fulfilling one of the two conditions would be more appropriate (i.e. <50 staff (WTEs) or <£10m turnover)? If so, which?***
***Question 6: If not, on what basis should small and micro providers be exempt?***

Again, the logic behind this is reasonable (to avoid burdening small organizations with administrative costs). However, we note that the impact assessment is in any case somewhat unclear about the scale of the administrative burdens, because so much of the guidance and detail has yet to be determined. .

We believe that it would be helpful to develop some broader criteria to assess the threshold, that take into account not only the scope of these provider organizations, (particularly in relation to the range of services that they offer and the communities of patients that they serve) but also the regulatory background. . If choice, competition, integration and robust costing data are considered to be important building blocks for improving efficiency and quality in the NHS as a whole, it is reasonable to assume that even smaller providers should be included.
Any criteria developed should be transparent and include a focus on proportionality (reducing administrative burdens) but also risk (whether are they providing essential services and their relationship with others services, for example whether they responsible for a large number of referrals) and avoiding duplication (whether is there already some regulation of the organisation, for example a charity will have to meet charity commission rules on governance and financial reporting compared to a GP partnership, which is subject to almost no financial or governance oversight but will have some quality oversight from revalidation).

**Question 8: Do you agree that providers of primary medical services and primary dental services under contracts with the NHS Commissioning Board should initially be exempt from the requirement to hold a licence from Monitor?**

We would reiterate our concerns expressed in question 1: for this exemption to be meaningful, the NHS Commissioning Board would need to apply the same data gathering and surveillance standards being used by Monitor. This will be important in relation to choice, competition and integration. As the consultation document mentions, general practice has been the primary location for the implementation of patient choice of provider in the NHS to date. Since the discontinuation of the Department of Health's patient choice survey in 2009, it is not clear how systematically GPs are offering patients information and choice when they are eligible for a choice of provider for non-urgent hospital care. Will there be any patient choice surveys in future? Will patient organizations such as Healthwatch be able to refer concerns about individual GPs failing to offer choice to the NHS Commissioning Board or Monitor for investigation? How will the Commissioning Board or commissioning groups assess whether GPs are offering patients meaningful choices?

Similarly, there has been concern about potential conflicts of interest arising as a result of the new clinical commissioning groups, when constituent GPs come together to innovate new forms of provision. If GPs are exempt on the grounds of duplication or size, the Commissioning Board needs to specify how it will monitor and respond to anti-competitive behaviour. Monitor's draft licence specifies that it will continue the current regime of 'ex-post' investigation of anti-competitive behaviour (ie when an organization makes a complaint), however the potentially large scale of primary care innovation might require a more proactive stance, if public confidence in GP referral decisions is to be maintained.

**Questions 10-21:** Do you think providers of adult social care who also provide NHS services should be required to hold a licence, unless they fall below a *de minimis* threshold?

We would reiterate the points made in relation to small scale providers of health services. There is a clear logic to include social care providers at some point in a regime of transparent information to facilitate pricing and choice, coupled with a demonstrable need to develop a workable failure regime. However, given the larger proportion of small scale providers, the potential administrative burden remains a concern.