How has the NHS been changed by the Health and Social Care Act 2012?

David Lock QC : June 2013

The purpose of this lecture is to attempt to look at the big themes in healthcare law in order to understand how the legal structure of the NHS has changed as a result of the passing and almost complete implementation of the Health and Social Care Act 2012. Inevitably there are other factors that change the NHS at the same time and I will attempt to weave in these other factors at an appropriate place.

I should admit at the outset that I was heavily involved in assisting the Labour Front Bench to respond to the Health and Social Care Bill. I worked with colleagues to understand and respond to the myriad of issues which were raised by this legislation. I therefore do not come to this topic as a neutral observer.

However there are a number of points that need to be made at the outset. First, there were many within the Conservative Party who were pushing for a far more radical reform of the NHS than that proposed in the White Paper of July 2012[1]. There were many who wanted to privatise large sections of the management of the NHS and others who wanted to convert the NHS into an insurance-based system. These individuals had considerable influence but did not, in the end, secure the policy objectives they were seeking.

Secondly, there are far more similarities between the NHS before and after the implementation of the Health and Social Care Act 2012. Care for patients remains largely free at the point of use[2] and the structural division of the NHS between commissioners and providers has largely remained unchanged. In fact there is an argument that the

[1] One of these voices was Nick Seddon who is now the No 10 policy advisor on health. For details of Mr Seddon's previous utterances see http://nhsrationing.org/2013/05/10/what-does-nick-seddons-appointment-tell-us-about-the-nhs-thinking-of-the-government/

[2] There have always been charges for prescription drugs in the community (but not in hospital), dental care and eye care.

Government could have achieved 95% of what it was seeking to achieve in this highly complicated Bill simply by changing the format of the Boards of primary care trusts in order to include more General Practitioners. I should make it clear that I do not entirely subscribe to that view for reasons that will become apparent during this lecture. However that is not what the government decided to do and instead presented one of the most complicated pieces of legislation that has ever been through the Parliamentary process.

Thirdly, the changes to the NHS brought about by the 2012 Act are profoundly ideological. The core of the Bill is Part III which seeks to turn the NHS into a market for the purchase of healthcare services. These changes will lead to substantial changes in the way the NHS functions. However, the creation of the market and the problems arising from procurement and competition law were nascent in the NHS before 2012, even though they were largely ignored.

Fourthly, reform of the NHS has often revolved around tensions concerning the “N” in the title. How much is the NHS a “national” health service and how much is it a series of local health services which operate independently of each other, only joining up when needed. The NHS has always had a tension between local decision-making and the delivery of national policy. Local decision-making is often seen as a “good thing” but it carries the inevitable implication that different localities will make different decisions. When decision are made in favour of particular patients this is celebrated as effective localism. When it works against the interests of particular patients it is decried as being "postcode prescribing".

The extent to which local NHS bodies should be entitled to make their own decisions about treatment priorities is a key political problem. No Secretary of State has wanted to be the decision maker who decides against NHS funding for named drugs or treatments. We saw this in the debates about the availability of Herceptin for some breast cancer sufferers in about 2005/6 when many local NHS bodies decided that this drug did not represent cost-effective medical treatment. The Secretary of State came under huge pressure from politically powerful lobby groups to use her influence to ensure the NHS provided Herceptin for all patients who may have been able to benefit from the drug, even though these were

local decisions. Patricia Hewitt bowed to this pressure by issuing very strong guidance even though the trial data suggested that only showed that 1 in 18 women provided with the drug would get any measurable benefit from it[3].

Fifthly, it is important to recognise that the NHS has never had enough money to fund health care interventions for all patients who had a clinical need for that intervention and could benefit from it[4]. This is not just in areas like IVF treatment but also in mental health support, community care for the elderly, district nursing and a huge number of other areas. The NHS budget has been substantially increased in recent years, and far more NHS funded medical treatment has been provided as a result; but it has never been enough. The NHS is now in an era of public spending cuts. However much the NHS is being protected within commented spending round, the problems at Accident & Emergency today have far more to do with cuts in social care budgets than the GP contract in 2004[5].

My sixth initial point is that change to the NHS is not all driven either by government policy or by legislation. The recent Francis Report made 290 recommendations and, if implemented, will result in profound cultural change within the NHS. It may well be that, if the Francis changes are successfully implemented, they will have as more effect than the 2012 Act in changing the nature of the experience of patients who use the NHS.

The structure of the NHS before the 2012 Act was that the Secretary of State had a statutory duty to provide healthcare services to patients but he also had power to delegate that duty to local NHS decision makers. The Secretary of State retained the power to direct that certain of his functions should be carried out by a local NHS body[6] and had power to issue "Directions" to require all NHS bodies to do or refrain from doing anything set out in a

[3] For details of the way that the Secretary of State responded to the pressure from lobby groups around herceptin see http://www.guardian.co.uk/society/2005/nov/09/health and the subsequent case of R (Rogers) v Swindon NHS Primary Care Trust & Anor [2006] EWCA Civ 392 at http://www.bailii.org/ew/cases/EWCA/Civ/2006/392.html

[4] See *R v Cambridge Health Authority ex p B* [1995] 1 WLR 898 at 906D for example.

[5] I am a Director of a major NHS Foundation Trust and it is impossible to move patients through the hospital if social care patients cannot be moved out of hospital because of social care budget cuts when it clinically appropriate to do so.

[6] Section 7 of the NHS Act 2006

Direction[7]. A Secretary of State's Direction creates an absolute legal obligation for an NHS body to comply with its terms. In due course the previous Government decided that direction making power would not apply to NHS Foundation Trusts, as we shall see below, and it has now largely been repealed.

In order to describe the impact of the changes imposed on the NHS by the 2012 Act, it is necessary to explain how the NHS was structured before the 2012 Act. Medical care in the NHS is provided by doctors, nurses and other healthcare professionals. Each healthcare professional has a private law duty of care to the patient that the individual professional is treating. This duty of care requires the healthcare professional to give the best possible care to the individual who stands before them. But the treatment options available to the doctor or nurse may be constrained by policy decisions taken within the NHS. Hence, for example, a doctor may feel that it is in the best interests of the patient to have IVF treatment but the woman may not qualify for NHS funded IVF treatment under the relevant NHS commissioning policy because of her age, weight or the presence of other children within her family. The doctor cannot breach his private law duty of care to the patient by failing to provide treatment which the NHS is unwilling to fund.

Until April 2013 the primary legal obligation to "provide" health care services rested on the Secretary of State. Section 1 of the NHS Act 2006 placed a duty on the Secretary of State:

> "continue the promotion in England of a comprehensive health service designed to secure improvement—
>
> (a) in the physical and mental health of the people of England, and
> (b) in the prevention, diagnosis and treatment of illness"

The precise wording of the section 1 statutory duty is important. It was a statutory duty to promote a comprehensive health service not a duty to provide such a service. The Court of Appeal has recognised in a series of cases that section 1 sets up a target duty but resource

[7] Section 8 of the NHS Act 2006.

limits mean that a comprehensive health care service will never in fact be delivered[8]. The Secretary of State must exercise his functions to aim at this target even if he will never achieve the objective of a comprehensive health service. Section 1(2) of the 2006 Act then provided:

> "The Secretary of State must for that purpose [*i.e. for the purpose of promoting a comprehensive health service*] provide or secure the provision of services in accordance with this Act"

Section 3(1) of the 2006 Act then imposed a specific statutory duty on the Secretary of State as follows:

> "The Secretary of State must provide throughout England, to such extent as he considers necessary to meet all reasonable requirements—
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> (a) hospital accommodation,
> (b) other accommodation for the purpose of any service provided under this Act,
> (c) medical, dental, ophthalmic, nursing and ambulance services,
> (d) such other services or facilities for the care of pregnant women, women who are breastfeeding and young children as he considers are appropriate as part of the health service,
> (e) such other services[9] or facilities for the prevention of illness, the care of persons suffering from illness and the after-care of persons who have suffered from illness as he considers are appropriate as part of the health service,
> (f) such other services or facilities as are required for the diagnosis and treatment of illness"

[8] See *R (Coughlan) v North and East Devon Health Authority* [2001] QB 213 for example.
[9] The provision of "other services" under section 1(3) as defined by the Secretary of State is the origin of the vires for the NHS to fund accommodation and social care under NHS Continuing Healthcare.

The duty on the Secretary of State to "provide" ambulance services does not, of course, mean that the Secretary of State must take the wheel of every ambulance in the country. The Secretary of State can delegate the duty to provide services to NHS bodies who then employ healthcare professionals to deliver services. However the judgement as to who does and who does not have a “reasonable” requirement for NHS services is a matter for the judgement of the Secretary of State. The Secretary of State delegated the exercise of that judgment to local NHS commissioners who made decisions about how to allocate resources between different patient groups.

In order to deliver on the section 3 duty the NHS has a variety of relationships with the medical professionals who provide NHS care. It has always been a "mixed economy" with some care provided by medical professionals who are employees of state bodies and other care provided by medical professionals who operate within the "for-profit" sector, contracting with the state to provide their services. There is an emerging and important role for the non-profit sector.

The NHS has been divided into "purchasers" and "providers" since the early 1990s. The division between parts of the NHS which commission services and parts of the NHS which provided services was an established part of the landscape well before the 2012 Act[10]. The purchasers were rechristened "commissioners" in the early years of the Labour government but their function was essentially the same. Their role was to conduct a health needs analysis for their populations[11] and then commission services from a range of provider organisations in order to meet as much of the health needs as the budget permitted.

These commissioning organisations started out as Health Authorities, became Primary Care Groups and then became Primary Care Trusts. These were quangos - corporate bodies set up by the Secretary of State with a lay Chair, executive and non-executive directors. When they were created from 2000 onwards, primary care trusts both commissioned services and provided community health services through their own staff, setting up notional contracts –

[10] NHS Trusts as separate provider Trusts were created by the NHS and Community Care Act 1990, which came into effect in 1992/3.
[11] See section 24 of the NHS Act 2006.

service level agreements – between different parts of the PCT. However from about 2007 the policy of the Labour government was that primary care trusts should only commission services and that there should be a corporate separation between commissioners and providers[12]. That programme resulted in PCT provider services being transferred to newly formed NHS community trusts, NHS trusts which delivered both community and mental health services, Community Interest Companies which delivered NHS services and private companies that won tenders to deliver services. Thus, for example, Assura (now part of Virgin Health) delivers NHS community services for the NHS in Surrey.

NHS commissioning organisations remained as primary care trusts but rebranded themselves so that Shropshire Primary Care Trust was known as "NHS Shropshire". However this was a change of brand but not a change of substance. These organisations were primary care trusts trading under a different name.

Whilst there were loud objections to the "privatisation" of NHS services in Surrey and elsewhere, the reality is NHS services have always been provided by a mixture of commercial and NHS suppliers, as well as those acting in the non-profit sector. GP practices and dental practices are examples of services being delivered by individuals who are either self-employed or employed by a company/partnership which is contracted to the NHS.

Most general practitioners and dentists have never been employees of the NHS[13]. GPs have arranged themselves in medical practices where the GP is both the medical professional providing care and is a part owner of the commercial business within which the professional services are provided. Partners in GP practices largely operated under a statutory scheme until 2004, but all general practice is now provided under contracts. Some GPs now own multiple practices and have developed very substantial businesses as a result[14].

[12] This was known as the Transforming Community Services or TCS programme.
[13] There were a small number of general practices owned by NHS bodies, mainly in areas where recruitment of private sector GPs was difficult. These were phased out as part of the TCS programme.
[14] 22 GP practices in Liverpool have recently been put out to tender. It was won by SSH Health, a company run by husband and wife team Dr and Dr Pitalia. This company provides GP services for over 100,000 patients. See http://www.ssphealth.com/

However private-sector provision of NHS care extends beyond primary care. Patients who are entitled to "NHS Continuing Healthcare", which is the provision of a package of health and social care services, including accommodation, to those with complex and/or unpredictable healthcare needs outside of the hospital environment, is usually delivered by commercial or non-profit providers. Care homes, nursing homes, specialist residential centres for clients with particular medical conditions and a whole range of other specialist services are provided by charitable and commercial organisations that contract into the NHS.

There has also been a long history of mental health services being provided by non-NHS providers, including organisations such as St Andrews Hospital[15] in Northampton which provides services to a large number of NHS patients who are detained under the Mental Health Act 1983. Some areas of public health are provided by independent providers. I am a trustee of the national charity Brook[16], which provides excellent sexual health advisory services to young people. It is contracted by the NHS to provide the services in various locations across the country[17].

However major NHS hospitals and providers of most mental health services have remained state bodies. When the purchaser/provider split in the health service was created in the early 1990s, these hospitals were formed into NHS trusts. An NHS trust is a corporate body - a quango - where the Board members constitute both executives and non-executive members[18]. There has always been a perceived "democratic deficit" in the operation of NHS trusts because, as originally set up, they had no effective accountability to the community they served. In practice, they were subject to performance management by the Department of Health which was managed through Strategic Health Authorities from about 2003 onwards. It was therefore a substantially upwards only process of accountability.

[15] See http://www.stah.org/
[16] See http://www.brook.org.uk/
[17] Many abortion clinics are also in the independent sector, contracting with NHS commissioners in order to provide services to patients who have passed through the necessary legal hoops in order to qualify for an abortion.
[18] An NHS Trust is not part of the Crown: see schedule 4 to the NHS Act 2006.

This was changed to some extent by the introduction of local authority Overview and Scrutiny Committees[19]. of the relevant local authority, that is the local authority who discharge social functions. Members of the Overview and Scrutiny Committee were required to be consulted on any substantial change in the delivery of local health services and, if they disagreed with the proposed change, were entitled to refer the proposal to the Secretary of State for final decision[20]. This created a measure of local accountability for local NHS services.

Thus if, as has happened regularly since 2002, the local authority objects to a reconfiguration of local health services, the Overview and Scrutiny Committee were entitled to refer the matter to the Secretary of State for a final decision before the local hospital was downgraded or the maternity unit was closed.

I should also refer to the fact that the Secretary of State set up the Independent Reconfiguration Panel ("the IRP") to provide advice to the Secretary of State. The IRP is hugely knowledgeable about the clinical evidence about the benefits of integration of acute care services and therefore has largely tended to support unpopular changes to local hospital services. In practice until 2010 the IRP provided political cover to the Secretary of State in allowing him or her to support decisions which were medically justifiable but were also deeply unpopular.

Prior to April 2013, decisions about "who was entitled to what NHS care" were primarily decisions taken by primary care trusts. It was the job of each PCT to have policies which defined the extent to which any patient was entitled to funding to support a particular healthcare procedure. Thus, for example, each PCT had its own policy concerning entitlement to IVF treatment. In contrast there was a national framework for determining which patients were entitled to NHS Continuing Healthcare ("CHC"). However even with CHC, the package of services that an eligible patient received was a matter for the local decision of the PCT. PCT policies define what level of services should be provided to NHS patients and set the terms of contracts with the NHS and private sector providers who

[19] Introduced by the Health and Social Care Act 2001, and then set out in section 244 of the NHS Act 2006.
[20] See the Local Authority (Overview and Scrutiny Committees Health Scrutiny Functions) Regulations 2002.

deliver NHS care to patients. Thus the twin levers of control for NHS commissioners to keep the budget under control are policies and contracts.

Whilst it has been the policy of successive governments that NHS decisions should be taken locally and not in Whitehall, prior to 2013 there were a number of mechanisms used to restrict the freedom of local NHS commissioners to decide what health care interventions should be funded for their local patients.

The Labour government set up NICE - the National Institute for Health and Clinical Excellence. The idea of NICE was to evaluate evidence at a national level concerning the clinical effectiveness and cost-effectiveness of healthcare interventions, and then to produce Guidance which would set the standards for local decision-making. There are 2 types of guidance produced by NICE. Technology Appraisal Guidance – or "TAGs". A TAG is formal guidance produced after a long and complex process. The Secretary of State issued Directions in 2003 requiring each primary care trust to make resources available to fund NHS treatment where a NICE TAG has recommended a particular intervention. Thus, for example, the problem of disparities between different areas of the making Herceptin available to NHS patients was solved when the NICE TAG "recommended" that this drug should be made available to certain categories of patient with breast cancer. The combination of the NICE TAG and the Directions meant that primary care trusts came under a legal obligation to fund Herceptin treatment of these categories of patients. This legal obligation is placed on NHS commissioners by Regulation 7 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013[21].

There is however a substantial amount of guidance produced by NICE which is not Technology Assessment Guidance. The status of this Guidance is that NHS commissioners are obliged to have regard to the guidance but they can depart from it if they have a good reason to do so[22]. Setting financial priorities in a way which does not provide sufficient

[21] See http://www.legislation.gov.uk/uksi/2013/259/contents/made
[22] See R (Fisher) v Derbyshire Health Authority (1997) 38 BMLR 76.

resources to be able to fund a particular type of treatment in accordance with NICE guidance has been accepted by the Court of Appeal as amounting to a good reason[23].

The NHS has also produced extensive "National Service Frameworks" which define best practice in a series of areas. However these tend to be created by committees of experts, who are also enthusiasts, for a particular treatment area of treatment. Accordingly, whilst NSFs undoubtedly contain much best practice, there has been less emphasis on whether the recommended care pathways represent the best use of limited NHS resources. Providing treatment in accordance with an NSF may represent best practice for the patient but it may not be cost-effective use of limited NHS resources. An NSF constitutes guidance but there is no legal obligation on local NHS commissioners to deliver services in accordance with the pathways set out in an NSF.

It is also important to make reference to the NHS Constitution[24]. This document sets out a series of policy statements about the NHS. There was a considerable debate in government about the extent to which the NHS Constitution should give patients enforceable legal rights. Those who argued "let's not make this a lawyer's charter" won that argument because section 2(1) of the Health Act 2009 provides that NHS bodies:

> "must, in performing its NHS functions, have regard to the NHS Constitution"

Section 2(5) provides that other organisations that contracts to provide NHS services must also "have regard to the NHS Constitution". The expression "have regard to the NHS Constitution" has only been considered once by the High Court, and the judgment did not go beyond reproducing the statutory words[25]. However this statutory duty is likely to be interpreted as a process obligation rather than an outcomes obligation, and thus will have a

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[23] See *R (Condliff) v North Staffordshire PCT*[23] Mr Condliff was clinically suitable for bariatric surgery because he had a Body Mass Index of 43 and the NICE guidance recommended this surgery for patients who had a BMI of more than 40. The local PCT policy departed from NICE guidance because it provided that NHS funding would be available routinely for patients who had a BMI of more than 50. This was held by the Court to be a lawful policy.

[24] See http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Pages/Overview.aspx

[25] See *R (Booker) v NHS Oldham & Anor* [2010] EWHC 2593 (Admin), which may well have been wrongly decided for reasons that go beyond the terms of this lecture.

similar status to the duty to have "due regard" to the interests of protecting groups under section 149(1) of the Equality Act 2010[26]. In practice it is very difficult to see any decision taken by the NHS body which is required to be changed as a result of the provisions of the NHS Constitution.

Each year (prior to 2013) the Chief Executive of the NHS has published an NHS Operating Framework which sets the priorities that he hopes the NHS will focus on in the coming year. These documents were, in a legal sense, "Guidance" to all NHS bodies to assist them to make discretionary decisions in accordance with nationally set priorities. In practice NHS managers who wish to remain in the job (and non-executives who wish to remain in post) have paid very close attention to the priorities set each year in the Operating Framework. This was, however, policy at a high level and did not define the entitlement of any particular patient group to any particular treatment.

There are also numerous other bodies[27] which publish "Guidance" in the hope that it will influence commissioning decisions of local NHs commissioners. Guidance by government departments has official status and therefore a local NHS Commissioner would be obliged to consider the guidance before making a relevant decision. All other guidance documents are matters that a local NHS Commissioner is entitled to take into account but is not obliged to do so.

Before turning to the changes brought about by the 2012 Act is necessary to say little about the legal structures of NHS Foundation Trusts. In the alphabet soup of the NHS, NHS Foundation Trusts are significantly different to NHS Trusts.

[26] See for example Aiktens LJ in *R (on the application of Brown) v Secretary of State for Work and Pensions* [2008] EWHC 3158 (Admin) at §90ff.

[27] The list of bodies that publish "Guidance" that can affect how NHS bodies discharge their duties is very extensive. It ranges from statutory bodies such as the General Medical Council whose guidance affects how medical professionals will respond to NHS policy through to All-Party Parliamentary Groups whose reports are often written by lobby groups advocating increased NHS investment in their area of interest (and in turn funded by industry interests who would benefit if that investment were to be provided).

NHS Foundation Trusts of public benefit corporations which have "members", who are normally resident in the geographical area served by the NHS Foundation Trust[28]. These members appoint the Chairman and Directors of the Trust who serve in a non-executive capacity, and have the ability to remove them from office. The non-executives then appoint the executive directors. Accordingly the legal structures of accountability of an NHS Foundation Trust are downwards towards their members rather than upwards to the Secretary of State.

NHS Foundation Trusts contract with NHS commissioners to provide of secondary care to NHS patients. There are however some crucial differences between NHS Foundation Trusts and NHS Trusts including:

a) NHS Foundation Trusts are regulated by a separate regulator, known as Monitor. Monitor[29] approves applications by NHS Trusts to become Foundation Trusts and grants them terms of authorisation. It has substantially concentrated on financial regulation of NHS Foundation Trusts but has been increasingly influential in clinical matters as well. The precise boundary between the regulatory influence of Monitor and the Care Quality Commission, which is the statutory regulator of public and commercial providers of health and social care services, including NHS trusts, remains somewhat opaque;

b) Arrangements between NHS commissioners and NHS trusts are set out in "NHS contracts". An NHS contract does not lead to legally enforceable rights on the part of either party[30]. However arrangements between an NHS Commissioner and an NHS Foundation Trust cannot be in an NHS contract. They are set out in legally enforceable contracts between the parties; and

[28] There are some highly specialist NHS FTs like Papworth who provide services to patients throughout the country and thus have no defined geographical area.
[29] Section 31 of the NHS Act 2006 affirms the existence of the "Independent Regulator of NHS Foundation Trusts". The 2012 Act changed the official name to Monitor. See section 61 of the 2012 Act.
[30] See section 9 of the NHS Act 2006.

c) NHS Foundation Trusts are independent of the Secretary of State because he has never had power to issue Directions to an NHS Foundation Trust. If Monitor considers that an NHS Foundation Trust is "*contravening, or failing to comply with, any term of its authorisation or any requirement imposed on it under any enactment and that the contravention or failure is significant*"[31], Monitor has the ability to issue directions to the Foundation Trust. However there is a clear separation between the independent regulator and the Secretary of State.

That was the broad legal structure of the NHS which was inherited by the coalition government when it came into power in May 2010. Shortly after coming into power the coalition government took 2 significant steps, namely issuing policy on the "4 tests" for reconfiguration and introducing the White Paper on NHS Reform. Both change the way the NHS operates.

First, in recognition of the political anguish caused by unpopular local reconfigurations of NHS services, the new Secretary of State, Andrew Lansley, signalled a change in policy by introducing the "4 tests" for reconfiguration of NHS services. In the period running up to May 2010 Conservative candidates up and down the country had been championing the causes of local NHS services which were under threat[32]. Although there were no doubt areas of genuine grievance, the evidence base to support improved clinical outcomes from centralisation of services is considered by many within the NHS to be overwhelming. The recent changes to NHS services in London for patients who have suffered a stroke has produced dramatic improvements in outcomes. Services are now concentrated on just 8 sites where specialists (and sub-specialists) have treated stroke patients to agreed protocols with substantially improved clinical outcomes[33].

However removing any service from a local NHS hospital is almost universally unpopular. Conservative candidates had made numerous promises on the election trail and many were

[31] See section 52 of the NHS Act 2006.

[32] It may have some significance that one of the primary supporters in the campaign which opposed down grading of services at the Royal Surrey Hospital was Jeremy Hunt, MP, now Secretary of State for Health. See http://www.savetheroyalsurrey.org.uk/

[33] See for example http://www.guardian.co.uk/healthcare-network/2012/jul/03/stroke-care-success-london-nhs

now elected. In order to make good on these promises the Secretary of State signalled a new approach to reconfiguration of NHS services. Four new tests were set out in a letter sent by the Chief Executive of the NHS, Sir David Nicholson, to NHS bodies on 19 May 2010. The letter explained that the Secretary of State had decided that no reconfigurations should proceed unless the following 4 tests were satisfied:

1. Support from GP commissioners will be essential;
2. Arrangements for public and patient engagement, including local authorities, should be further strengthened;
3. There should be greater clarity about the clinical evidence base underpinning proposals.
4. That proposals should take into account the need to develop and support patient choice.

There were, of course, at this stage no "GP commissioners". Commissioning of NHS services was undertaken by primary care trusts not by GPs. Nonetheless the letter from David Nicholson explained that there would be a moratorium on existing reconfigurations and that:

> "Future reconfiguration proposals will be expected to meet clear standards in each of these areas ..."

This letter was followed by an article in the Daily Telegraph dated 20 May 2010 in which the policy justification for the new 4 tests was explained. It was written by the Secretary of State[34] and said:

> "The first duty of any health service is to serve its patients – to ensure that people do not have to fit their lives around an inflexible system, but that the system bends to fit them. It sounds like a simple aim, yet too often in recent years, the reality has been quite different.

[34] See http://www.telegraph.co.uk/health/7747870/The-NHS-must-put-patients-first.html

> Perhaps the most frustrating example of this is the closure of local A&E and maternity units around the country – against the wishes not just of clinical staff, but also of the communities that they are there to serve. It reminds me of Bertolt Brecht's dark joke that a government which has lost the faith of its people and is contemplating reform might find it easier simply to "dissolve the people and elect another"

That approach ignored the fact that many of these unpopular changes had been the subject of detailed consideration by the Independent Reconfiguration Panel which had examined the clinical evidence and decided the changes were beneficial for patients.

The Secretary of State's article explained that the policy response of the government to a situation where A&E and maternity services at a local hospital were proposed for closure in the face of substantial local opposition was the introduction of the "four tests" for reconfigurations which was supposed to ensure that the situation described above could not happen. The Secretary of State then went on his article to describe the introduction of the tests as follows:

> "As of today, I am calling a halt to the current process. I have asked Sir David Nicholson, the chief executive of the NHS, to inform the service of this immediately and to signal a complete change to the way we deal with these issues. This moratorium will provide a chance to reset every proposal, to reconsider every decision and to ensure that in each case they are consistent with the following key criteria.
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> First, there must be clarity about the clinical evidence base underpinning the proposals. Second, they must have the support of the GP commissioners involved. Third, they must genuinely promote choice for their patients. Fourth, the process must have genuinely engaged the public, patients and local authorities.

This will not merely be another tick-box exercise – it will be a tough test, which every proposal must pass if it is to proceed.

More importantly, this will not be about me, as the Secretary of State, going back over these decisions. This time the power won't be at the centre, it will be at the grassroots – in the hands of the patients, the communities and the clinicians who are directly involved. The critical point is that the key criteria are met.

So I am issuing a challenge to GPs to work with community leaders and their local authorities, to take the reins and steer their local services to meet the quality standards and achieve the outcomes that people expect.

It is time we recognised that the real headquarters of the NHS is not on Whitehall, it's wherever there are patients, it's the doctors and nurses whom we register with at our local practice. These are the people whom we rely on and trust. They should be the ones making the decisions about the management of our services as well. That is how we will create a service that is centred on the needs and the wishes of patients.

And it is only by pushing power to the front line that we will get away from the stultifying focus on inputs and processes that has dominated the healthcare debate.

I've talked to staff in hundreds of hospitals, surgeries and clinics across the country and there's one thing predominant in their minds – how to improve the service and care they provide to their patients.

By instituting this moratorium and putting patients and clinicians in control we are taking a first, and immediate, step towards improving outcomes and creating a less centralised, less bureaucratic, stronger NHS”

There is a strong legal argument that the statements made by the Secretary of State within this article, either read by itself or in conjunction with the published statutory framework, constituted a clear promise made in a public document by the Secretary of State that NHS reconfigurations would not happen unless the 4 tests were met.

The revised 2010 Operating Framework for the NHS was published on 21 June 2010. Paragraph 15 was headed "New rules on reconfiguration". It said:

> "These [*referring to specific reconfiguration proposals referred to earlier in the paragraph*] and any other current and future reconfiguration proposals must meet four new tests before they can proceed. These tests are designed to build confidence within the service, with patience and communities"

This document repeated the 4 tests set out in the newspaper article and in the letter of 20 May 2010, namely:

- support from GP commissioners;
- strengthened public and patient engagement;
- clarity on the clinical evidence base; and
- consistency with current and prospective patient choice.

Further Guidance on the meaning of the 4 tests emerged from Sir David Nicholson in a letter dated 29 July 2010.

Whether the clear policy announcements set out above give rise to any legal obligations on the government will be tested in the Judicial Review concerning the downgrading of Lewisham Hospital which is due to take place in the High Court on 2 – 4 July 2013. As I am instructed in that case it would not be appropriate me to give any predictions as to which way it is likely to go, save to say that it is hard to envisage the court saying that the above statements of policy had no legal effect whatsoever.

The second major development following the election of the coalition government was the publication of a Health White Paper in July 2012 "Equity and Excellence: Liberating the NHS"[35] which signalled radical change for the organisation of the NHS. It is slightly ironic that the coalition agreement, which itself is not a legally binding document but which had been signed a few weeks earlier promised[36]:

> "We will stop the top-down reorganisations of the NHS that have got in the way of patient care"

The White Paper set out policy proposals for radical change in the NHS. These were substantially carried forward in the Bill that the government subsequently published and now take effect in the Health and Social Care Act 2012. It would be possible to describe the ebb and flow of policy proposals throughout this process, including the ubiquitous "pause" in the middle of the parliamentary passage of this legislation, but that is probably best left to political anoraks. All I can do in the time available to me this afternoon is to give an overview of the effect of the changes to the way that the NHS is set up and operates.

The original legislation which governs this was the National Health Service Act 1946, and then the National Health Service Act 1977. The 1977 Act was then amended on numerous occasions between 1977 and 2006. The law relating to the NHS consolidated in the National Health Service Act 2006 but the 2006 Act was then amended on numerous further occasions after it was passed. One of the difficulties in understanding the effect of the Health and Social Care Act 2012 is that the 2012 Act followed the same structure as all previous Health Acts by amending the previously consolidated NHS Act.

Thus all the material amendments introduced by the 2012 Act take effect as changes to the 2006 Act. However the changes to the 2006 Act introduced by the 2012 Act were very substantial, and hence some of the section numbers are extremely difficult to follow. For example the section which defines arrangements by clinical commissioning groups in

[35] See https://www.gov.uk/government/publications/liberating-the-nhs-white-paper
[36] See https://www.gov.uk/government/publications/the-coalition-documentation

respect of their functions is now in section 14Z3 of the 2006 Act! We can only hope that a new consolidated Act will emerge at some point in the near future.

There are a series of structural changes to the NHS created by the 2012 Act, but it is not possible to list all the changes in one lecture or I will still be here long after you have all gone home. So let's look at the main changes.

The first key change to note is that public health functions have been transferred from NHS bodies to local authorities[37], which now need to appoint a Director of Public Health. Public health functions are often unseen by the general public but they include health promotion and the planning and response to anything which presents a risk to public health. Nationally the Health Protection Agency is now part of the Department of Health. This was a sensible and logical change because, in some areas, the power for public health functions has always remained with the local authority. For example an application to transfer a patient with an infectious disease to hospital under the Public Health (Control of Disease) Act 1984 required an application to be made to the magistrates court by the "proper officer of the local authority for that district".

Secondly, the 2012 Act created the National Health Service Commissioning Board. The Board has now decided that it is to be known as "NHS England". The Board has a number of different functions. However, at a high level, it now shares with the Secretary of State the section 1(1) duty to continue the promotion of a comprehensive health service. It also has specific duties to commission a range of services throughout England, notably:

a) GP and dental services (primarily because conflicts of interest prevent these being commissioned by clinical commissioning groups, which are lead by GPs);

b) Specialised services[38]. There are a huge variety of specialised services for patients with relatively rare conditions which are now commissioned by NHS

[37] Where the local government structure provides for both county and district councils, public health functions are transferred to the county council in order to co-exist with social services functions.
[38] See http://www.england.nhs.uk/tag/specialised-services/

England, along with specialised acute medical services for patients with more general conditions such as chemotherapy. The budget for specialised services for 2013/14 accounts for approximately 10% of the total NHS budget, namely about £11.8 billion per annum;

c) Health services members of the Armed Forces;

d) Prison medical services;

e) High secure psychiatric services[39].

NHS England is also responsible for the system of Performance Lists for primary care professionals. All medical professionals who wish to deliver primary medical services to NHS patients are required to be registered on the NHS England Performers List. This is a form of individual regulation which sits alongside the General Medical Council for doctors, the Nursing and Midwifery Council for nurses and a variety of other regulators[40].

The Chief Executive of NHS England is Sir David Nicholson. Sir David has signalled his intention to retire with effect from March 2014. Perhaps liberated by the prospect of life away from ministerial control, he recently gave a speech at the NHS Confederation conference which emphasised his vision of the independence of NHS England from the Secretary of State, as well as containing thinly veiled criticism of the present and previous Secretary of State[41]. He described NHS England as:

> "an organisation that was capable of looking ahead, of getting us out of the tyranny of that electoral cycle, to think about the NHS over the medium to long-term"

[39] There is a useful fact sheet published by NHS England which explains the division of commissioning between CCGs and NHS England at http://www.england.nhs.uk/resources/resources-for-ccgs/
[40] for more details please see National Health Service (Performers Lists) (England) Regulations 2013 and Guidance published by NHS England on the management of the Performers List functions. See http://www.performer.england.nhs.uk/
[41] See http://www.england.nhs.uk/2013/06/06/sir-david-nicholson-speech/

The role of the Secretary of State is now confined to providing a "Mandate" to NHS England[42]. This is a formalisation of the NHS Operating Framework, the non-statutory "Guidance" document, which was published by the Chief Executive of the NHS each year. The Mandate set out the objectives that the Secretary of State considers NHS England "should seek to achieve in the exercise of its functions" and must specify:

> "Any requirements that the Secretary of State considers it necessary to impose on the Board for the purpose of ensuring that it achieves those objectives"

The Mandate is close to giving the Secretary of State the power to impose directions on NHS England. However this direction making power can only be done through the annual mandate giving process and cannot be done as and when a crisis emerges. The duty on NHS England is to "seek to achieve the objectives" but, in doing so, it has a statutory duty to comply with any requirement in the Mandate specified by the Secretary of State.

The other major function undertaken by NHS England is the licensing and performance management of clinical commissioning groups. The 2012 Act abolished primary care trusts and replace them with clinical commissioning groups. Clinical commissioning groups are membership organisations whose primary role is to commission NHS services for the people in their area. The members of the local GP practices are all members of their local CCG.

Section 3(1) of the 2006 Act now reads:

> "A clinical commissioning group must arrange for the provision of the following to such extent as it considers necessary to meet the reasonable requirements of the persons for whom it has responsibility ... "

The range of services which each CCG has a responsibility to commission is the same as the healthcare services which Secretary of State was previously required to provide. But the duty to provide these services is no longer on the Secretary of State.

[42] See section 23 of the 2012 Act, which introduced a new section 13A to the 2006 Act.

There are a series of specific statutory duties on both NHS England and clinical commissioning groups. These include:

a) A duty to promote the NHS Constitution;

b) Duties to exercise their functions effectively, efficiently and economically;

c) A duty to promote "autonomy". This is not a duty to promote the autonomy of patients but a duty to let providers of NHS services deliver services in the way they think best. CCGs must have regard to the desirability of securing that anyone providing services can :

> "... exercise those functions or provide those services in the manner it considers most appropriate"

d) A duty to exercise its functions having regard to the need to reduce inequalities between patients with respect to their ability to access health services and inequalities between patients with respect to the outcomes achieved for them by the provision of health services. This inequality duty is likely to be the subject of considerable litigation, particularly arising out of resource allocation between different patient groups;

e) A duty to promote innovation in the provision of health services.

The local arm of the Department of Health, Strategic Health Authorities, are abolished by the 2012 Act. However in practice their functions have been taken over by the Local Area Teams of NHS England.

One substantial change has been the removal of the power of the Secretary of State to issue Directions against local NHS commissioners and providers. This is part of the vision of the Secretary of State being responsible for setting the strategic framework but not being

responsible for every operation. It is the final abandonment of the vision of the first Secretary of State for Health, Aneurin Bevan who created the service nearly 60 years ago based on the principle that if a bedpan dropped in a hospital corridor, the reverberations should echo in Whitehall.

Directions cannot now be issued by the Secretary of State to require a CCG to do something or refrain from doing something. The 2012 Act proposes the removal of the Secretary of State's direction making power in respect of NHS Trusts. Unsurprisingly that last element has not yet been implemented. Nonetheless the 2012 Act has seen the political master of the NHS move from a practical to a strategic role. It was interesting to see the response of the Secretary of State to the recent problems in Accident & Emergency. There was little evidence that, faced with a crisis, the Secretary of State was prepared to leave the resolution that crisis to local NHS leaders and we saw NHS England intervening to force NHS Foundation Trusts to improve their performance on the 4 hour target (even though the majority of the problems lie well outside A & E Departments). Perhaps the vision of a detached and strategic Secretary of State promoted by Andrew Lansley is not shared by his successor.

There are an enormous number of other changes as a result of the 2012 Act but the final area I wish to discuss this afternoon is the changes to the internal market arrangements within the NHS set out in Part 3 of the 2012 Act.

Part 3 of the Act shows the government's approach to the vexed question of the extent to which the NHS should be treated as a market. Compulsory competitive tendering has made a profound difference to local authorities but it is the dog which is not yet barked within the NHS. EU procurement law does not apply to internal arrangements within one public body or a set of public bodies which are under the control of a single public body. This is the so-called *Teckal* exemption to EU procurement obligations[43]. It means that the EU imposed obligations of transparency, equal treatment and non-discrimination do not generally apply when an NHS commission places a contract for NHS services with an NHS trust. However an

[43] For details of the *Teckal* exemption see *Brent London Borough Council and others v Risk Management Partners Ltd* [2011] UKSC 7: http://www.bailii.org/uk/cases/UKSC/2011/7.html

unintended side effect of the creation of NHS Foundation Trusts is that the *Teckal* exemption to EU procurement obligations was swept aside. This was substantially recognised in Guidance issued by the previous government in 2008[44].

The Public Contracts Regulations 2006 imposed duties of transparency, non-discrimination and equal treatment on a wide variety of "contracting authorities". Primary care trusts were not specifically mentioned in the Public Contracts Regulations 2006 but almost certainly come within the extended definition of contracting authorities to whom the regulations apply[45].

Whilst the rigid procedures defined in the Public Contracts Regulations 2006 do not apply to NHS contracting because these are “Part B” services, the duty of transparency has been interpreted by the European Court to require "a degree of advertising" before any public contract is agreed[46]. Primary care trusts were taking their duties more seriously in areas such as tendering for GP contracts, but there is no tradition of market testing for acute services contracts which are set out in contracts with NHS Foundation Trusts. In particular many contracts were let as part of the Transforming Community Services program, when community services previously provided by staff employed by primary care trust were outsourced, which made little or no attempt to comply with the principles of transparency. These issues have, as far as I'm aware, only been tested in the High Court once in *R (Ota Lloyd) v Gloucestershire Primary Care Trust* where the decision to award a contract to an in-house Community Interest Company was challenged by local residents. The PCT defended the position by saying they were relying on government guidance, which was arguably correct. However departmental guide does not normally override fundamental principles of

[44] See the PCT Procurement Guide for Health Services: Department of Health (2008)

[45] See Regulation 3(1)(w) which provides “a corporation established, or a group of individuals appointed to act together, for the specific purpose of meeting needs in the general interest, not having an industrial or commercial character, and—

(i) financed wholly or mainly by another contracting authority;

(ii) subject to management supervision by another contracting authority; or

(iii) more than half of the board of directors or members of which, or, in the case of a group of individuals, more than half of those individuals, are appointed by another contracting authority.

A primary care trust receives all its money from the Secretary of State and is subject to direction by the Secretary of State, and it's members are appointed by the Secretary of State. It follows that a primary care trust appears to qualify under each of these limbs.

[46] See for example *Telaustria Verlags GmbH v Telekom Austria AG (Case C-324/98)* [2000] ECR I-10745 and a series of further cases in the European Court.

the European Treaty. The PCT effectively conceded the challenge of the first day in court and so there was no judgment to explain how NHS procurement principles operated in the circumstances.

All this has been changed by the 2012 Act which has focused a bright light on procurement within the NHS. Section 75 permits this Secretary of State to make Regulations to impose procurement requirements on NHS England and clinical commissioning groups. However the sting in the tail is in section 76(7) which provides:

> "A failure to comply with a requirement imposed by regulations under section 75 which causes loss or damage is actionable, except in so far as the regulations restrict the right to bring such an action"

Hence a commercial healthcare supplier who ought to have been provided with the chance to bid for the chance to provide NHS services and has been wrongly excluded from the chance to take part in a competition has a right to seek damages from the NHS commissioner.

The relevant regulations of the National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013[47] which came into force on 1st April 2013.

Monitor has now published 53 pages of draft Guidance about how NHS commissioners should interpret the Regulations[48]. However in many areas the Guidance is attempting to row back from the terms of the Regulations themselves.

The objective of proper procurement in the NHS is set out in Regulation 2 which provides:

[47] See http://www.legislation.gov.uk/uksi/2013/500/introduction/made These were the second set of Regulations because they were changed after political objections were raised about the first set. However there is no significant difference between the old and new Regulations for present purposes.
[48] See http://www.monitor-nhsft.gov.uk/node/3352

> "When procuring health care services(1) for the purposes of the NHS (including taking a decision referred to in regulation 7(2)), a relevant body must act with a view to—
>
> (a) securing the needs of the people who use the services,
> (b) improving the quality of the services, and
> (c) improving efficiency in the provision of the services,
>
> including through the services being provided in an integrated way (including with other health care services, health-related services, or social care services)"

The Regulations apply to every single contract for any type of healthcare service which is placed by a CCG or NHS England, including NHS contracts, unless the commission is satisfied that services can only be provided by one capable provider. In practice it seems that they will be very few occasions when the "single capable provider" condition will be satisfied.

Where there is a competition NHS commissioners have a duty to act in a transparent and proportionate way and to treat providers equally and in a non-discriminatory way, including by not treating a provider, or type of provider, more favourably than any other provider, in particular on the basis of ownership[49].

The duty of acting a transparent way is particularly onerous as this word has a wide meaning within EU procurement law. Monitor's draft Guidance suggests that the following elements have to be satisfied by an NHS Commissioner:

> "In considering whether commissioners have complied with their general duty to act transparently, Monitor may consider, for example, the extent to which commissioners have:

[49] See Regulation 3.

- published information on their future procurement strategies and intentions;
- taken steps to ensure that providers are aware of their intention to procure particular services, including by publishing contract opportunities;
- when procuring services, provided feedback to any providers that have offered to provide services that have been unsuccessful;
- published details of the contracts they have awarded in a timely manner; and
- maintained suitable records of the key decisions that they have taken (including the reasons for those decisions).

There is also no lower financial threshold and accordingly every single contract needs to be the subject of a proper procurement process. When an elderly patient is placed by the NHS in a care home because the patient is eligible for NHS Continuing Healthcare, the CCG contracts for a package of care from the care home. Such contracts are now subject to the principles of transparency, non-discrimination and equal treatment, and accordingly the opportunity to enter into that contract ought to be advertised on a website hosted by NHS England before the contract is placed.

There are no provisions in the contract for urgent contracts and nothing in the statutory scheme which allows a CCG to take account of preferences expressed by the patient or relatives. The contract must be placed by applying the twin objectives of:

a) identifying the provider that is most capable of delivering the objectives referred to in regulation 2 in relation to the services, and
b) provides the best value for money in doing so.

Whilst "value for money" does not necessarily mean the lowest price, the specific reference to value for money will inevitably make price a far more important factor in future contracting decisions.

There are also clear statements about the limited circumstances in which NHS contracting can be undertaken in a way which is anti-competitive. Much of the debate around the circumstances in which NHS commissioners might be thought to be acting in an anti-competitive way has focused around the "bundling" of different types of medical service into a single contract. A hospital trust will want a single contract to deliver comprehensive acute services. It will also make the point that providing emergency services can only work within a hospital that provides a comprehensive range of 24-hour services in individual departments. However a private provider that simply provides, for example, routine orthopaedic operations may well be able to demonstrate that it can provide hip replacements at a lower cost than the local NHS Foundation Trust. In those circumstances it may complain that a single comprehensive acute services contract which includes routine elective hip replacements is anti-competitive.

These are arguments that have yet to be resolved but it seems almost inevitable that they will lead to litigation. The 2013 Regulations provide that Monitor should be available to adjudicate on disputes. However it is very difficult to see why a commercial contract would wish to have their dispute determined by Monitor rather than seeking to litigate the matter in the courts.

I hope that this overview of the 2012 Act has been useful in identifying the ways in which the NHS has changed in the last few years and how it is likely to change going forwards. In some senses the changes have not been as profound as claimed by either the proponents or those who were objecting. But the practical effect of the abolition of primary care trusts has taken away very considerable commissioning capability from the NHS and the GPs who form the boards of the new CCGs are facing a very steep learning curve. In principle greater clinical involvement in commissioning ought to be a good thing. The initial indications are that there is huge variation in the capability of local CCGs to rise to the challenges. There is a marked lack of management competence in this most difficult of managerial functions.

The introduction of the "4 tests" has made it increasingly difficult to carry out any form of rational reconfiguration of NHS acute services. There is an astonishingly wide consensus that

the NHS needs to move services out of hospitals and into the community in order to be able to deliver effective services to an increasing ageing population. But taking the difficult decisions needed to bring this about will require very considerable managerial and political skills.

Sir David Nicholson said in his recent speech to the NHS Confederation that

> "It is interesting, at the moment today as we sit here we have the lowest hospital mortality rates since records began. Every year over the last few years hospital mortality has fallen, it has gone down by about a half in the last 8 or 9 years. On the other side really bad things happen to some of our patients, sometimes we fail them and their families significantly. Now both of those things are true. The danger at the moment, if you talk about bad things that happen to our patients, lots of people say it is not true, what about the great things in the NHS? And if you talk about hospital mortality going down, it is almost as if you deny that there are problems in the NHS. The reality is both of them are true"

The key test the NHS in the coming years is to maximise the good things and minimise the terrible experiences of those let down by both individual healthcare professionals and the system. Major structural reform to the NHS appears highly unlikely to deliver it.

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