NHS Bodies, Procurement, the 2013 Regulations: How to avoid tying the NHS up in red tape.

There is something slightly ironic in a barrister giving a talk about the need to avoid tying things up in red tape because – of course – briefs for barristers traditionally arrive tied up in red – well actually pink – tape. However the origin of the phrase "red tape" was the Spanish administration of Charles V in the early 16th century, who started to use the red tape in an effort to modernise the administration that was running his vast empire. The red tape was used to bind the important administrative dossiers that had to be discussed by the Council of State, and separate them from the issues that were treated in an ordinary administrative way, which were bound by an ordinary rope. American Civil War veterans' records were also bound in red tape, and the difficulty in accessing them is said to have led to the modern American use of the term. There is no single definition of the concept of "red tape" but it usually conveys the idea of excessive regulation or rigid conformity to formal rules, which are excessively bureaucratic or hinders action or decision-making.

The issue I want to address over the 30 minutes or so is extent to which the legal structures imposed on the NHS shoehorn NHS decision makers into a "procurement" model which governs the organisation of NHS services even if that is antithetical to the interests of NHS patients.

Before looking at the National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013 it is necessary to identify 2 different perspectives on the structures of the NHS. The public see the NHS as a monolith organisation and speak of the NHS as one of the largest employers in the UK[1]. However the NHS is not a monolith but a network of different organisations that commissioner, provider and regulate healthcare. Almost all healthcare is delivered to NHS patients as a result of arrangements concluded between NHS commissioners and a variety of NHS, private and third sector providers. The

[1] NHS organisations throughout the UK employ an estimated 1.7M people, which is the 5th largest "employer" in the world behind the US Department of Defence (3.2m), The Chinese Army (2.3m) Walmart (2.1m) and McDonalds (1.9m).

essential features of these arrangements are that the NHS patient accesses services from the provider and the provider gets paid by the commissioner for the delivery of that service. The services are largely free at the point of use for the patient but the activity is measured, coded and charged back to the commissioners.

Many of these arrangements not legal contracts at all but "NHS contracts" which, as the Court of Appeal confirmed in *Pitalia v NHS England*[2] last month, do not give rise to legal obligations[3] and cannot be the subject of legal proceedings.

These arrangements give rise to radically different views of the NHS. Clinicians tend to see these arrangements between different notionally independent NHS bodies as internal service level agreements between essentially parts of a single overall public service. Hence the divisions between NHS bodies, at best, differentiate the different professional areas of medical practice and, at worst, are a distraction from the main business of providing care to patients. However this model of the NHS sees NHS bodies working co-operatively with each other, and where there is a conflict NHS bodies and other providers are expected to make their own interests second to the interests of patients.

However there is another view. This perspective sees the NHS as a giant market place where providers compete with commissioners for contracts as part of the healthcare supply chain which stretches from the Department of Health – which is allocated the tax payers money by Parliament through to the final service provider to the patient. Under this view of the "market" NHS, procurement and competition are essential features of the proper functioning of the NHS market. The broad purpose of procurement law, as expressed in the EU Directive is provide for a fair opportunity for all potential providers of services throughout the EU[4]. It is – to quote from recital 2 of the Directive of 2004/18 to promote:

> "principle of freedom of movement of goods, the principle of freedom of establishment and the principle of freedom to provide services and to the principles

[2] See [2014] EWCA Civ 474 which is reported at http://www.bailii.org/ew/cases/EWCA/Civ/2014/474.html
[3] See section 9 of the National Health Service Act 2006.
[4] For further details please see *R (Law Society) v Legal Services Commission* [2008] QB 737.

deriving therefrom, such as the principle of equal treatment, the principle of non-discrimination, the principle of mutual recognition, the principle of proportionality and the principle of transparency[5]"

The purpose of competition law is to prevent anti-competitive practices in order to promote wider choice, lower prices, better services and greater efficiency than under conditions of monopoly. The theory is that NHS providers who compete for work will deliver a more cost efficient service to commissioners and – hopefully – to patients.

The tension between these 2 views of the NHS has been rumbling away for years. Procurement was largely ignored in the main functioning of the NHS "internal market" because it was precisely that – an internal market. NHS contracts were not proper contracts and all NHS bodies were subject to directions made by the Secretary of State. Hence the *Teckal* exemption applied to NHS contracts[6]. However all has changed over recent years because:

a) When NHS Foundation Trusts were introduced in 2004, the arrangements with these new bodies were proper legally binding contracts and not NHS contracts;

b) NHS Foundation Trusts are not under the control of the Secretary of State because they cannot be "directed" under section 9.

The Labour government attempted to resolve the conflicts by setting up a "Co-operation and Competition Panel" which adjudicated on competition and procurement disputes between NHS bodies and others[7]. The principles under which the Panel worked stressed co-operation, planning for clinical outcomes and the interests of patients over the interests of the raw market.

[5] It was also supposed to be "necessary to meet requests for simplification and modernisation made by contracting authorities and economic operators alike"

[6] For an explanation of the *Teckal* exemption within the UK context see *Brent London Borough Council and others v Risk Management Partners Ltd* [2011] UKSC 7 at http://www.bailii.org/uk/cases/UKSC/2011/7.html

[7] For details please see http://www.nhsft-regulator.gov.uk/regulating-health-care-providers-commissioners/cooperation-and-competition/archive-co-operation-and--1 However most of the hyperlinks to the key documents appear not to be working!

However the implementation of the Public Contracts Regulations in January 2006 introduced legal rules to NHs contracting for the first time, at least as far as non-directable bodies were concerned. Although NHS contracts were "Part B" services[8] and hence outside the formal processes under Part 3 of the Regulations, the statutory duties in Part 1 largely applied to such contracts.

Thus an NHS commissioner[9] entering into an acute services contract above the financial thresholds set out in the Regulations with an NHS Foundation Trust was required to comply with the duties set out in Parts 1, 8 and 9 of the 2006 Regulations[10]. Thus all NHS commissioners were required to comply with the duties of equal treatment, non-discrimination and transparency set out in Regulation 4(3). These interlinked duties have been examined in a series of EU cases and, in *Telaustria Verlags GmbH v Telekom Austria AG*[11] the court said:

> "That obligation of transparency which is imposed on the contracting authority consists in ensuring, for the benefit of any potential tenderer, a degree of advertising sufficient to enable the services market to be opened up to competition and the impartiality of procurement procedures to be reviewed"

Most NHS acute services contract contracts are, of course, let without any form of advertising or tender procedure at all. There are, for example, 3 major acute Trusts in Birmingham[12] and, as far as I am aware, there has never been any advertising of the main acute services contracts even though these are annually renewed contracts worth hundreds of million pounds a year.

However there was no practical problem as long as no one challenged the NHS commissioners. Hospital services can only be provided by "hospitals" and the barriers to

[8] Health and social care contracts are in paragraph 25 of Part B to Schedule 3 to the 2006 Regulations.
[9] An NHS commissioner is a "contracting authority" as a result of Regulation 3(1)(w) of the 2006 Regulations.
[10] See Regulation 5(2) of the 2006 Regulations.
[11] See *(Case C-324/98)* [2000] ECR I-10745 [2000] All ER (D) 2168
[12] I sit as a non-executive director on one Trust, the Heart of England NHS Foundation Trust.

entry into this market are somewhat steep. So the legal rules under the 2006 Act were largely ignored.

However all that has changed with the Health and Social Care Act 2012 where the "market" theory of the NHS gained dominance over the "we're all in it together" theory. Section 75 of the 2012 Act permitted the Secretary of State to make Regulations to require NHS commissioners to "adhere to good practice in relation to procurement". The Regulations that followed were the National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013[13].

Before turning to the Regulations I must draw attention to section 76(7) of the 2012 Act 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 disappointed potential contractors who fail to be awarded NHS contracts which are awarded in breach of the terms of the Regulations are given the right to sue for damages in the courts.

Regulation 2 provides a target duty which sets out the general approach that NHS commissioners must take when procuring health services. It provides:

> "When procuring health care services 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,

[13] SI 2013/500. They are the No2 Regulations because the earlier version was abandoned after political howls of anguish. However, as usual, those who expressed themselves deeply opposed to the principles were bought off with a limited number of inconsequential changes but there was no change to the main principles. There are, at present, no reported cases on the interpretation of the Regulations.

(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)"

"Health care services" are not defined in the Regulations but this term is defined in section 64 of the 2012 Act to mean any provision of services for the purposes of the NHS Act 2006[14]. These are, of course, potentially conflicting duties but the Regulation appears to require NHS commissioners to balance the 4 considerations of meeting needs, improving quality, improving efficiency and promoting integration of both health and health/social care services.

The Regulations apply to decisions by NHS commissioners to enter into legally binding contracts to procure healthcare services and NHS contracts. There is also no *de minimis* financial level below which the Regulations do not apply.

The specific statutory duties are set out in Regulation 3. Regulation 3(2) provides that:

"The relevant body must—

(a) act in a transparent and proportionate way, and

(b) 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"

[14] Health care is very widely defined under section 64(2) to mean all forms of NHS health care provided to an individual even if it also amounts to social care.

This Regulation repeats the duties under the 2006 Regulations of transparency, non-discrimination and equal treatment. However there was an argument under 2006 Regulations that those duties only applied where the contract in question was of interest to economic operators located in another EU state[15]. If that argument ever existed it plainly does not apply now.

There is no definition of the meaning of these terms and accordingly no reason to interpret them differently to the meanings ascribed in the various EU cases. Thus the duty of transparency requires a "degree of advertising" to test the market and allow other potential operators the chance to express interest in providing services. The extended words on equal treatment mean that NHS commissioners cannot have a policy of favouring NHS bodies over private sector providers.

Regulation 3(3) provides that:

> "The relevant body must procure the services from one or more providers that—
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> (a) are most capable of delivering the objective referred to in regulation 2 in relation to the services, and
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> (b) provide best value for money in doing so"

The word "must" imposes a clear statutory duty on NHS commissioners to test the market because, if they do not do so, it is difficult if not impossible to see how they are able to demonstrate compliance with the above Regulation.

Regulation 3(4) contains a further set of requirements that NHS commissioners "must" comply with, namely:

[15] I always thought that this was an argument of dubious merit.

> "In acting with a view to improving quality and efficiency in the provision of the services the relevant body must consider appropriate means of making such improvements, including through—
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> (a) the services being provided in a more integrated way (including with other health care services, health-related services, or social care services),
>
> (b) enabling providers to compete to provide the services, and
>
> (c) allowing patients a choice of provider of the services"

There are clearly many different processes that NHS commissioners could follow to satisfy themselves of the obligations under this Regulation but commissioners are required to show some form of compliance with these detailed requirements for every contract.

The "red tape" emerges under Regulation 4(5) which sets out the recording obligations on an NHS body as follows:

> "A relevant body must, in relation to each contract awarded by it for the provision of health care services for the purposes of the NHS, maintain a record of—
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> (a) in the case of a contract awarded by the Board, details of how in awarding the contract it complies with its duties under sections 13D, 13E and 13N of the 2006 Act(1) (duties as to effectiveness, efficiency etc, improvement in quality of services and promoting integration);
>
> (b) in the case of a contract awarded by a CCG, details of how in awarding the contract it complies with its duties under sections 14Q, 14R and 14Z1 of that Act(2) (duties as to effectiveness, efficiency etc, improvement in quality of services and promoting integration)"

Regulation 5(2) provides that, where advertising an intention to seek offers from providers in relation to a new contract for the provision of health care services for the purposes of the NHS, NHS commissioners must publish a contract notice on the website maintained by NHS England[16]. The "contract notice" must include:

> (a) a description of the services required to be provided, and
>
> (b) the criteria against which any bids for the contract will be evaluated.

The circumstances in which an NHS commissioner does not need to go through a competitive process before awarding a contract are set out in Regulation 5 which provides:

> "A relevant body may award a new contract for the provision of health care services for the purposes of the NHS to a single provider without advertising an intention to seek offers from providers in relation to that contract where the relevant body is satisfied that the services to which the contract relates are capable of being provided only by that provider"

This is a very narrow exemption because it will not apply in any case where the services could be provided by more than NHS body or other provider. There are many hospitals in a city such as London and so it is difficult if not impossible to reach the view that any contract could come within Regulation 5.

There are a series of unanswered questions about these Regulations. In particular, local NHS commissioners are required to have detailed arrangements for involving patients generally in decision making about commissioning under section 14Z2 of the NHS Act. It remains wholly unclear how CCGs are supposed to operate a fair tender process under the 2013 Regulations whilst, at the same time, involving patients in commissioning decisions. It appears clear that a decision by a CCG that a particular service should be subject to a tender process is a decision which must involve patients. However it is unclear how the usual

[16] This is now at www.online.contractsfinder.businesslink.gov.uk

requirements of commercial confidentiality can be squared with public and patient engagement in decision making.

Secondly, the NHS has not build in any resources to meet the cost to the NHS of complying with the requirements of the 2013 Regulations. One leading firm of NHS lawyer has suggested that "the number of challenges in 2013 is roughly five times those in 2009". However before the Regulations were published the Department of Health Impact Assessment[17] said "There are negligible direct costs to patients, commissioners or providers" and that that indirect costs could not be estimated but "could be negligible". This may prove to have been somewhat optimistic.

Thirdly, and perhaps most crucially, how do rules on procurement and competition fit with planning patient flows which are necessary to ensure quality outcomes. There is a mass of research data which shows that better outcomes for patients are delivered and cost effectiveness improves if services are amalgamated in specialist centres. When the NHS in Bristol proposed centralisation of the provision and management of head and neck services at University Hospitals Bristol Foundation Trust and of breast care and urology at North Bristol Trust, this was subject to a Monitor inquiry because it potentially reduced competition in the provision of local services. Monitor eventually concluded that quality improvements borne of a recent reconfiguration of acute services in Bristol were not sufficient to outweigh the loss of patient choice resulting from the "merger", but stopped short of requiring the Trusts to reverse the decisions. But this approach sent a chilling effect through the NHS, showing that just showing that services were better for patients was insufficient to justify a perceived loss of competition in local services.

So the answer to the question posed at the outset of this talk is – I regret – that the NHS has Regulations which tie itself up in depressing amounts of red tape. In practice the NHS is very largely ignoring the Regulations.

[17] See http://webarchive.nationalarchives.gov.uk/20130402145952/http://media.dh.gov.uk/network/261/files/2013/02/2013-500-IA.pdf

To understand why these are unworkable end I would like to ask a colleague to come to the front so we can show how these Regulations would theoretically work when an elderly lady with complex medical needs is ready to be discharged from an acute hospital to a nursing home. The problem in this case is that the NHS commissioner has a detailed knowledge of the Regulations. The conversation ought to go something like this:

Hospital Manager: *Hello I am speaking to the CCG NHS Continuing Healthcare co-ordinator?*

NHS Commissioner: *Yes.*

Hospital Manager: *We have Mrs Jones ready to be discharged from our hospital. She's eligible for NHS continuing care and so will need a care home bed including some extra nursing support. The family have identified Sunnybank Care Home which has a bed, has a good CQC rating and is just around the corner from her daughter. The cost is £750 per week. Can you please confirm we can discharge her to Sunnybank.*

NHS Commissioner: *Thank you. I am happy to confirm we will make a decision for Mrs Jones in accordance with the National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013 in making this decision. As I understand it, you are asking for the CCG to enter into a contract with Sunnybank Care Home for the delivery of health care services to Mrs Jones. For the purposes of Regulation 5 of the Regulations can you please let me know if Sunnybank Care Home is the only provider who might be able to deliver services to Mrs Jones?*

Hospital Manager: *Well, there are obviously other providers who could deliver services to her but this is a suitable provider and it's the one that the family have chosen. The price seems about right and the NHS have used this home before so I assume that it would be OK.*

NHS Commissioner: *Thank you. I regret that, under the 2013 Regulations, before I can enter into a contract with Sunnybank Care Home I must run a competitive tender process to select the provider for the NHS which is most capable of delivering the objectives referred to in regulation 2 in relation to the services to be provided to Mrs Jones and I must also ensure the contracts provides the best value for money for the CCG.*

Hospital Manager: *What!! This is the NHS providing services for Mrs Jones, not the purchase of a new photocopier.*

NHS Commissioner: *The Regulations mean I must go through certain processes before I can lawfully enter into a contract with a provider of healthcare services, and that must include giving other potential providers the chance to bid. There is no escape from the rules!*

Hospital Manager: *But I need the bed for other patients. Can we place Mrs Jones at the home before you put a contract in place?*

NHS Commissioner: *Sorry but No. We cannot have a contract with Sunnybank Care Home until a provider is selected after a competitive tender process. If we placed Mrs Jones before that process was completed it would give Sunnybank Care Home a competitive advantage in the tender process over other potential providers. The CCG has a duty to treat all care home providers equally and it would breach that if we placed her at Sunnybank in advance of the competitive process. Sorry, she will have to stay in hospital until the tender process has finished.*

Hospital Manager: *How long will that be?*

NHS Commissioner: *We will need to prepare a specification of her needs to describe the sort of care she needs, and then we need to advertise the contract on the NHS England website to see if there are expressions of interest. The next stage will be for care homes who are interested in this contract doing will their own assessments of Mrs Jones to see if they want to bid for the contract and how much they will charge. Once we get all the bids in we will need to consult the family as part of the evaluation*

process and then take a decision about where to offer to place Mrs Jones. If we work really fast, don't get too many bids and have co-operation from the family, we might be able to get all this done in say 3 months. 6 months might be more realistic.

Hospital Manager: *That is ridiculous. Where will Mrs Jones have to stay in the meantime.*

NHS Commissioner: *I regret that I cannot agree to any new contract for Mrs Jones to be moved from your hospital until we have been through a proper procurement service under the new Regulations. She will have to stay in hospital.*

Hospital Manager: *But we need the bed for other patients.*

NHS Commissioner: *I am sorry. The patient cannot be moved without a contract being put in place, and the 2013 Regulations do not allow me to put a contract in place unless I have been through a tender process for Mrs Jones and every other patient who needs to be placed in a care home after 1 April 2013. She will have to stay in hospital.*