KEATING CHAMBERS

Nottingham Conference Paper: Competition in the new NHS - When should an NHS Commissioner go out to tender for clinical services?

Introduction

The UK National Health Service, product of the post war welfare state, star of the 2012 Olympic opening ceremony and national treasure, has undergone many changes in recent decades.

This paper considers the way in which competition has been introduced and assesses the implications for the application of public procurement law to healthcare services in the UK, following the introduction of NHS specific procurement rules and the light touch regime under Directive 2014/24/EU. It considers ways in which the full application of procurement law can be managed or mitigated to ensure that the viability of essential clinical services can be protected.

Background

The original NHS was a top down managed structure operating within a state guaranteed system to ensure a minimum level of healthcare to all, free at the point of delivery. It was based, to use an EU law term, on the principle of "solidarity" rather than competition.

In the early 1990s, providers of hospital (secondary) care became NHS Trusts with greater responsibility for their affairs. This achieved a "purchaser-provider" split from the buyer health authorities.[1]

Under New Labour, the National Health Service Act 2006 introduced Primary Care Groups (later Primary Care Trusts, "PCTs") as commissioners of services and consolidated legislation which enabled NHS Trusts to take on "Foundation Trust" status enjoying greater freedom and independence from Government, the ability to retain surpluses and access private capital and derive part of the turnover from non NHS sources (eg private patient units).

A new tariff system was introduced (payment by results) which enabled patients in their GP surgery to select their secondary care provider ("choose and book" later, "any qualified provider") with the money following the patient. This introduced an element of competition with a view to incentivising quality improvements (*eg* shorter waiting times). At the same time, from 2005 onwards, the Department of Health published (in the Official Journal of the EU) waves of tenders enabling

[1] See Lindsay Stirton, Back to the Future? Lessons on the Pro-Competitive Regulation of Health Services. Medical Law Review (2014) 22 (2): 180 for an excellent account of the development of competition and regulation in the NHS.

independent sector providers to bid for NHS contracts. These enabled the financing of new independent sector treatment centres. They also introduced private providers onto the "choose and book" menu for a wide range of diagnostic (*eg* MRI or PET-CT scans) and elective (*eg* hip replacements and knee operations) services. A non statutory set of rules was also introduced, "*the Principles and Rules of Cooperation and Competition*", with a view to enabling the Department of Health and a newly constituted advisory body, the Cooperation and Competition panel for NHS funded services, to oversee and manage the competition and procurement issues which were beginning to emerge and, possibly, to help transition the NHS towards a competition based system.

The Coalition Government took the reforms a stage further, with the Health and Social Care Act 2012, by (in addition to replacing PCTs with GP Commissioning Consortia Groups) turning Monitor into a utility style independent economic regulator, with tariff setting powers, a failure (administration) regime, concurrency (with the OFT, now CMA) in relation to the Competition Act 1998 and special powers to enforce sector specific procurement rules. Many of these reforms were controversial and were adopted only following heated debate in Parliament over the virtues and vices of competition for NHS services. The Labour opposition in particular declared its intention to repeal the reforms (in spite or perhaps partly because of them being the natural progression of changes introduced in the Blair years). However, the outcome of the 2015 election has no doubt ensured their survival for at least the next 5 years.

NHS Competition and Procurement

The controversy surrounding the 2012 Act is based on the concern that the social purpose, viability and integrity of the NHS may be undermined or removed as a result of the encroachment of markets and liberalisation of the sector. Competition and fair tendering are anathema to the idea of favouring NHS providers over private sector providers and this means that, unless the structure of competition is carefully managed, it is feared that publicly owned NHS hospitals will fail and close and essential services may be lost.

The unease with a utility model regulatory system is that healthcare is different and more complicated. Competition in the rail sector can be managed (not un-controversially) through periodic tender franchises. The water sector (and electricity transmission) has regional monopolies and is regulated through RPI plus tariff controls and comparative competition. Telecommunications is more competitive but, some 20 years after liberalisation, continues to feature a single dominant network provider and detailed access regulation. The other sectors regulated by a utility model have been privatised, whereas the public assets in the NHS have not been sold off.

The other key difference between the NHS and utility sectors is that NHS services are tax-payer funded and free at the point of delivery. Ultimately the State is the buyer of NHS healthcare services

and it is this feature which may trigger the application of the public procurement rules. However, the obligation to compete NHS services through fair and transparent tender procedures gives rise to all manner of problems.

Firstly, the range of clinical services provided by the NHS is huge and complex. Some of these are more amenable to competition than others, many are interdependent (*eg* forming part of the same care pathway or sharing resources) and the commissioner or consumer will often not know best to choose between providers. There are therefore concerns over information asymmetry (which hinders efficient competition), cream-skimming (where competition will develop from independent sector providers for the easier more lucrative services but leave other harder services under-funded) and what sort of competition works best.

On the one hand there is competition "in the market" where the patient calls off certain types of secondary care from qualified providers and on the other there is franchise-like competition for the market where providers may compete for example for a 5 year community services contract (eg for mental healthcare, diabetes, sexual health, minor injuries) worth hundreds of millions of pounds. There could even be competition for the provision of acute hospital services (eg Accident and Emergency).

Secondly, the structural changes brought about by the 2012 Act, which mean that commissioners are now consortia of GPs with clinical responsibilities and a day job, have made the commissioning side yet more fragmented and the difficulties are arguably made worse by the localised nature of commissioning, with no clear strategic mechanism for protecting essential services.

The challenges of achieving efficiencies in the NHS faced with ever increasing demand are hard enough without public procurement requirements. As explained below, the difficulty with introducing competition into the NHS is that this makes it more likely that the EU procurement rules (as well as competition law) will apply.

The response of Government has been to introduce NHS specific procurement rules. But do these NHS rules help with the above challenges or make things worse and how do they work alongside the EU public procurement rules, particularly now that a light touch regime has been introduced under Directive 2014/24/EU? Is it possible to find a way of ensuring that the State uses its position as sole buyer of NHS services to manage the sector in a more coherent way while complying with EU procurement obligations?[2]

I focus in this paper on the issue of <u>when</u> commissioners must go out to tender. There are many other challenges in <u>how</u> best to go out to tender – but these are covered by other papers.

[2] Any solutions would also need to ensure compliance with competition law but the further issues raised by competition law are not covered by this paper. See The King's Fund, Procurement and Competition Rules: Can the NHS be exempted?

The NHS Procurement Rules

The National Health Service (Procurement, Patient Choice and Competition) Regulations 2013 (SI 2013/500) (the "NHS Procurement Regulations"), were adopted on 6 March 2013 under section 75 of the 2012 Act. They replace an earlier version of the same Regulations (SI 2013/257), which had been made on 11 February 2013. The NHS Procurement Regulations come into force on 1 April 2013.

Version 1 was withdrawn, following opposition in Parliament and from healthcare professionals, and reissued in an attempt to address concerns raised that the new rules would force open NHS services to competition by introducing compulsory tendering. This outcry was somewhat overstated and, as further explained below, the NHS Procurement Regulations do not liberalise the NHS. They do, however, create a legally enforceable (either by Monitor or in the courts) sector specific procurement regime which operates in parallel with (and sometimes in opposition to, as explained below) the EU public procurement rules.

NHS commissioners (CCGs or the NHS Commissioning Board for services procured centrally, such as specialised services) must, under Regulation 3(3) of the NHS Procurement Regulations, procure the services from the provider(s) most capable of delivering their objectives (of securing patient needs, quality and efficiency) and providing best value for money. Regulation 3(4) of the NHS Procurement Regulations lists the strategies that commissioners must consider to improve service quality and efficiency. This includes the option of enabling providers to compete to provide the services but there are other options, including "*service integration*".

Competitive tenders (or accreditation plus patient choice) may be an effective means of demonstrating that Regulation 3(3) and (4) have been complied with.

However, commissioners must also weigh up their duties of economy, effectiveness and efficiency and this may mean that a cost benefit analysis is undertaken before embarking on an advertised tender process. In some cases, the cost and resources required to tender a contract may not be justified by the potential gain from competition. Further, there may be wider cost and clinical implications if the incumbent provider loses a contract following a competitive tender. The mix of duties may then point commissioners towards <u>not</u> tendering even where there is more than one potential bidder.

There is also a generous sole supplier exemption under Regulation 5(1) of the NHS Procurement Regulations, which has been interpreted widely by Monitor in its guidance (*Substantive guidance on the Procurement, Patient Choice and Competition Regulations* of December 2013 at page 41).

There are other requirements which may be unwelcome to commissioners including an unprecedented obligation on commissioners not to act in an anti-competitive manner. And the NHS Procurement

Regulations do not provide a clear solution to some of the challenges raised above, relating for example to the need to ensure that the financial viability of essential core services is maintained within the NHS.

However, in procurement terms the NHS Regulations appear to give some flexibility and recognition of the difficult task that commissioners are faced with in balancing up their various priorities. So far, so good.

The EU Procurement Rules

The difficulty is that EU procurement law applies as well. Under the Public Contracts Regulations 2006 (the "2006 Regulations")[3], health care services were classified as "Part B services". For these services, there were few procedural requirements and no express obligation to advertise. The 2006 Regulations do therefore sit reasonably well alongside the NHS Regulations.

However, where a healthcare service (or other Part B) contract is sufficiently large or has other features that may potentially attract cross border interest there is an obligation under EU single market principles to conduct an appropriately advertised tender process, unless there is an applicable derogation or exemption[4]. This based on the notion that the Treaty on the Functioning of the European Union ("TFEU") is engaged only by contracts having a sufficient connection with the functioning of the Internal Market.[5]

NHS providers as economic operators?

There is a question as to whether the award of public healthcare contracts to NHS providers engages the EU Treaty at all and an argument that at least some of these contracts fall outside the remit of the procurement rules. Directive 2014/24/EU defines "*public contracts"* as:

"contracts for pecuniary interest concluded in writing between one or more economic operators and one or more contracting authorities"

The question is whether NHS Trusts are always or just sometimes "economic operators". The concept of an economic operator has been interpreted by the EU courts as meaning an operator pursuing a market activity. In *Commission v Italy*[6], the Court of Justice found that the fact that the Italian Red Cross was a not for profit company did not take it outside the scope of the public procurement rules. In doing so, the Court drew on the competition law jurisprudence on the definition of an "undertaking"[7] and concluded that as providers of patient transport services are undertakings, "*It*

[3] These implement Directive 2004/18/EC.
[4] *Telaustria C-324/98, Germany v Commission Case T-258/06.*
[5] Ibid. See also *Coname* (C-231/03).
[6] *Commission v Italy* (C-119/06) (not reported in English).
[7] *AOK* (C-264/01, 306/01, C-354/01 and C-355/01), *Ambulanz Glockner* (C-475/99).

follows that the organisations concerned may pursue an economic activity in competition with other operators".[8]

There is a credible argument that NHS providers are only economic operators in relation to activities which have been exposed to competition. This may, at least in England, include an increasing range of diagnostic and elective secondary care services, community services and primary care services[9]. However, it does not necessarily include the provision of core acute hospital based services, such as accident and emergency and a range of specialist consultant services. These services, it may be argued, have not been liberalised and continue to be provided, using state funded assets, albeit controlled in the case of NHS Foundation Trusts by independent entities, on a non-commercial and exclusively social[10] basis and do not therefore engage the TFEU.

The way in which the commissioner-provider split and competition in the NHS has evolved, as considered above, may not have been orchestrated in the best way possible to avoid the EU procurement rules, but in essence the argument would be that the vast majority of the £120 billion or so spent annually in the UK on NHS services is not spent on market activity which engages the TFEU and continues to be reserved to the State. Neither the TFEU nor Directive 2014/24/EU require Member States to liberalise sectors and States are allowed to reserve to themselves the provision of public services.[11] This argument works best where hospitals continue to be run by NHS Trusts which are subject to the direction and control of the Secretary of State under the NHS Act 2006 (NHS Acute Trusts). There is a tension between the autonomy granted to Foundation Trusts and the argument that the sector has not been liberalised.

However, it is clear that where NHS commissioners consider that a particular contract, if tendered, might attract bids from non-UK providers and the NHS provider with whom it has traditionally contracted might now be considered an "economic operator" by virtue of the existence of actual or potential competition for the services in question this could trigger an obligation under EU law to tender the contract. In practise, this dilemma may arise every year when NHS clinical service contracts are renewed, generally with the local NHS Trust.

There is therefore already a certain tension between EU law and the NHS Procurement Regulations. By virtue of the sovereignty of EU law, any national rules which conflict with EU law are automatically inapplicable (*Simmenthal Case 106/77 [1978] EC R 629*). If, therefore, the EU rules apply and there is an inconsistency with the NHS Regulations, an English court would resolve it in favour of the EU rules.

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[8] Ibid Paragraph 41: "*Il en résulte que les associations concernées peuvent exercer une activité économique en concurrence avec d'autres opérateurs*."

[9] Which are in any event performed by private partnerships of GPs.

[10] See Public bodies and competition law, OFT December 2011. Exclusively social services are those which by their very nature could not be carried out for profit and for which market activity therefore plays no role. See AG Jacobs in *AOK* ibid. Such services are governed by the principle of "solidarity" rather than economic or market activity. See also *Poucet and Pistre* (C-159/91).

[11] See Preamble 5 and 6 to Directive 2014/24/EU.

It is rare for legal challenges to be brought under the EU procurement rules to a decision not to tender a contract and the same is true of NHS contracts but the uncertainty and risk is there.

The situation is not improved by Directive 2014/24/EU which introduces the light touch regime in Articles 74 to 75.

The Light touch Regime

This regime (implemented in the UK by Regulations 74 and 75 of the Public Contract Regulations 2015 ("the 2015 Regulations") require services certain types of former Part B healthcare, cultural, social or educational services contracts which are above a new higher threshold of €750000 to be advertised in the OJEU enabling interested operators to express their interest and tender on a fair and transparent basis. While the light touch regime is flexible as to how to go out to tender and Regulation 76(7) allows for all relevant considerations to be taken into account in awarding contracts, the rules require a competitive tender process. This is subject to the exemptions or exclusions in the Regulations, but there is no cost/benefit or wider clinical interests' exemption and the sole supplier exemption (Regulation 32(2)(b)) is narrowly drawn (see below).

In proposing the light touch regime, the European Commission appears to have taken the view that the cross border interest test under *Telaustria* created too much uncertainty and assumed that any contract above the new threshold would attract potential cross border interest and should therefore be tendered. One difficulty with this is that most clinical service contracts are likely to exceed this threshold. Another is that it does not address the difficulties that tendering may give rise to in a public healthcare system. It also strengthens the hand of a potential challenger to an untendered NHS contract.

There was perhaps a squandered opportunity here to provide a suitable exemption for publicly funded healthcare systems by expanding on and clarifying the distinction between economic and social operators and making it clear that the contract awards to the latter are not subject to the light touch regime.

The UK approach has also arguably not helped matters. The UK took an early adopter approach to the new Directive by implementing one year ahead of the April 2016 deadline. However, when it came to the NHS it took a different position.

Regulation 118(3) of the 2015 Regulations provides that the 2006 Regulations continue to apply to healthcare services within the meaning of the NHS Regulations until April 2016. This means that contracts for NHS health care services let by NHS England and Clinical Commissioning Groups (CCGs) will fall outside the new procurement regime in the interim period. This appears to recognise that NHS commissioned services are subject to the new rules, when it might have been possible to make clear from the outset that there may be doubt over the issue.

The Crown Commercial Service states in its Guidance document[12] that this delay is to give commissioners time to adapt. It may also reflect the fundamental tension between the light touch regime and the NHS Regulations - the NHS Regulations provide a basis for a no tender decision based on a balanced assessment of various commissioner duties, whereas the light touch regime does not. If the two sets of rules deliver different answers the 2015 Regulations will trump the NHS Regulations by virtue of the supremacy of EU law.

As explained above, the requirement on commissioners across England[13] to tender NHS clinical services gives rise to many challenges and may threaten the viability of essential public services. So are there derogations or other bases under the Directive to provide flexibility to commissioners and avoid the conflict with the NHS Regulations?

Possible Exemptions and Derogations

One exemption to the obligation to advertise under the light touch regime is the sole supplier exemption.[14]

This is available (Regulation 32 of the 2015 Regulations) *"…where the works, supplies or services can be supplied only by a particular economic operator for any of the following reasons:—*

(i)the aim of the procurement is the creation or acquisition of a unique work of art or artistic performance,

(ii)competition is absent for technical reasons,

(iii)the protection of exclusive rights, including intellectual property rights,

but only, in the case of paragraphs (ii) and (iii), where no reasonable alternative or substitute exists and the absence of competition is not the result of an artificial narrowing down of the parameters of the procurement;

The difficulty with applying this exemption to NHS service contracts is that the evidence of recent years is that private healthcare groups or indeed other NHS Trusts will be often be able and willing to bid for a wide range of clinical services. There have even been tenders in the UK for the management of a whole district general hospital.[15]

Another potential exemption is the in house exemption under Article 12 of the new Directive (Regulation 12 of the 2015 Regulations), which codifies the *Teckal*[16] case law.

[12] Guidance on the new light touch regime for health, social, education and certain other service contracts.
[13] Healthcare is devolved in the UK and the regimes in other parts of the UK do not feature the commissioner-provider split, autonomy of Foundation Trusts and provider competition to quite the same extent as in England.
[14] Regulation 75 provides that the obligation to advertise does not apply where *a negotiated procedure without prior publication could have been used, in accordance with regulation 32, for the award of a public service contract.*
[15] Though ultimately with limited success in the case of Hinchingbrooke Hospital.
[16] C-107/98.

***"12.**—(1) A public contract awarded by a contracting authority to a legal person falls outside the scope of this Part where all of the following conditions are fulfilled:—*

(a)the contracting authority exercises over the legal person concerned a control which is similar to that which it exercises over its own departments;

(b)more than 80% of the activities of the controlled legal person are carried out in the performance of tasks entrusted to it by the controlling contracting authority or by other legal persons controlled by that contracting authority; and

(c)there is no direct private capital participation in the controlled legal person with the exception of non-controlling and non-blocking forms of private capital participation required by national legislative provisions, in conformity with the Treaties, which do not exert a decisive influence on the controlled legal person.

As indicated above in relation to the definition of economic operators, this exemption may work in relation to contracts awarded to NHS Acute Trusts which are subject to Secretary of State directions, but will not do so for autonomous NHS Foundation Trusts.

A further derogation which may be available for clinical service contracts with NHS Acute Trusts is based on the requirement that a public service contract must be legally enforceable to trigger the procurement rules. Given the non binding status of NHS contracts (*ie* contracts between commissioners and NHS Acute Trusts), there is a good argument that these contracts are not subject to the light touch regime.[17] Again this does not help, under current law, in relation to contracts with NHS Foundation Trusts.

A potentially more promising exemption is through the use of "*exclusive rights*" to protect services of general economic interest.

Regulation 11 of the 2015 Regulations provides that:

"This Part[18] does not apply to public service contracts awarded by a contracting authority to another contracting authority on the basis of an exclusive right which the latter enjoys pursuant to a law, regulation or published administrative provision which is compatible with TFEU."

This would involve (a) entrusting (through a law, regulation or administrative provision) providers (whether NHS or in some cases private) with "*services of general economic interest*", the continuity and financial viability of which are essential to patient interests and (b) granting sufficient exclusive rights to enable the providers to perform these services.[19] If providers were granted exclusive rights, the service contracts would either be excluded from the Regulations by Regulation 11 (where the provider is a contracting authority) or exempted from the obligation to publish a prior notice under Regulation 32(2)(b)(iii).

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[17] *Helmut Muller* (C-451/08).

[18] The light touch regime is within the same Part as the other substantive obligations under the 2015 Regulations.

[19] See TILEC Discussion Paper of May 2008, Service of general economic interest and universal service in EU law by Wolf Sauter. In *Corbeau* (C-320/91) it was made clear that while the grant of any exclusive rights would need to be proportionate to the delivery of the SGEI the exclusivity could cover services which were wider in scope where necessary to ensure the funding of the SGEI.

The grant of such exclusive rights would need to be consistent with EU law, notably Article 106 of the TFEU.[20] However, it seems likely that a case could be made for these based on protecting the viability of essential healthcare services (such as A&E and a range of services which are clinically or financially interdependent with A&E).

Such a solution would give rise to controversial questions – the nature and duration of exclusive rights, the choice of providers, the legal mechanism used to grant the rights, how much top down control would be exercised over commissioners, what consultation requirements may apply *etc*. However, it would offer a strategic approach to determining the pace and direction of NHS competition.

Conclusion

Whether competition in NHS provision and the specific regulatory regime introduced to address this (the 2012 Act and NHS Regulations) is a good thing or not, it certainly gives rise to challenges under the EU procurement rules. These challenges have been accentuated by the light touch regime under the new Directive and there is an imminent threat of conflict with NHS specific rules when the Directive is fully implemented. Tools are available under the Directive and general EU principles to manage the conflict in a manner which protects the viability of core NHS services. The transitional period under the 2015 Regulations (to April 2016) has given the government time to consider this. However, time is running out on a solution to curb the unbridled application of the light touch regime and protect the treasured provision of free at the point of delivery healthcare in the UK from the potentially erosive effects of unmanaged competition.

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[20] *106(2). Undertakings entrusted with the operation of services of general economic interest or having the character of a revenue-producing monopoly shall be subject to the rules contained in the Treaties, in particular to the rules on competition, in so far as the application of such rules does not obstruct the performance, in law or in fact, of the particular tasks assigned to them. The development of trade must not be affected to such an extent as would be contrary to the interests of the Union.*