

Procurement regulations for NHS healthcare services: big bang or business as usual?

This article examines the National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013 (SI 2013/500) (the NHS Procurement Regulations), which were made on 6 March 2013. 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Version 1 was effectively withdrawn, following an outcry from the political opposition and healthcare professionals, and reissued in an attempt to address the concerns raised.

The concerns raised were that the NHS Procurement Regulations would force open NHS services to competition by introducing compulsory competitive tendering. In other words, that the regulations would effect a big bang, liberalising the sector and opening it up to private providers.

The article analyses the NHS Procurement Regulations and their possible implications, including their effect on tendering obligations, Monitor's powers to enforce the new rules, and the interaction between the regulations and competition law. It also assesses how far the amendments made address the big bang fear.

Content of NHS Procurement Regulations

The NHS Procurement Regulations are adopted further to section 75 of the Health and Social Care Act 2012 (the Act). Section 75 refers to the purpose of securing that, in commissioning NHS healthcare services, the NHS Commissioning Board (NHSCB) and clinical commissioning groups (CCGs):

- Adhere to good procurement practice.
- Promote and protect patient choice.
- Do not engage in anti-competitive behaviour which is against patient interests.

The main elements of the NHS Procurement Regulations are:

- **Objectives.** When procuring NHS services, commissioners must act with a view to securing patient needs, improving service quality and improving service efficiency. To these were added the words “*including through the services being provided in an integrated way*” in the revised version. (*Regulation 2*)
- **General requirements.** These include that commissioners must:
 - act in a transparent and proportionate way, treat providers in a non-discriminatory way and not favour one provider over another on the basis of ownership;
 - procure from the provider(s) most capable of delivering the objectives above and providing best value in doing so;
 - consider appropriate means of improving quality and efficiency, including through service integration, competition to provide the services and patient choice; and
 - record how in awarding the contract they comply with their statutory duties (to exercise their functions effectively, efficiently and economically and so as to improve the quality of services and, inserted by the reissued version, of promoting integration). (*Regulation 3*)
- **Advertisement.** NHSCB is to maintain a website to be used for contract records and for advertising the intention to seek offers, such adverts to include bid evaluation criteria. (*Regulation 4*)
- **Contract awards without competition.** This will be permissible where a commissioner is satisfied that the services are only capable of being provided by one provider.

A further rider that this would only be the case for technical reasons, reasons connected with the exercise of exclusive rights or in the event of extreme urgency due to events unforeseeable by and not brought about by the commissioner appeared in the first version but was removed from the revised version. (*Regulation 5*)
- **Conflicts of interest between commissioner and provider.** Commissioners must not award a contract where a conflict affects or appears to affect the integrity of the award and a record should be made of how any conflict was managed. (*Regulation 6*)
- **Qualification of providers.** Commissioners must establish and apply transparent, proportionate and non-discriminatory criteria to:
 - determine lists of providers from which patients may choose (with no limit in relation to choice of provider and team for first outpatient appointments);

- determine framework providers; and
- select bidders for a future contract. (*Regulation 7*)
- **Records.** Records of all contracts awarded are to be kept and published, including provider details, service description, value, dates and the process adopted. (*Regulation 9*)
- **Anti-competitive behaviour.** When commissioning NHS healthcare services, NHSCB and CCGs must not engage in anti-competitive behaviour unless to do so is in the interests of patients, including where (added to the revised version) services are being provided in an integrated way or by cooperation between providers to improve service quality.

NHS service arrangements must not include restrictions of competition that are not necessary for the attainment of intended beneficial patient outcomes or overall objectives. (*Regulation 10*)

(An exception to these rules where necessary to ensure compliance with a UK or EU legal requirement was provided in the first version but removed in the revised version.)

- **Primary care.** Patient choice of provider must not be restricted. (*Regulation 11*)
- **Monitor.** Will have:
 - wide powers of investigation, including to obtain documents, explanations and e-mails, but no power to investigate where an action has been brought under the Public Contracts Regulations 2006 (*SI 2006/5*) as amended (the Public Contracts Regulations);
 - the power to declare a NHS healthcare service arrangement to be ineffective, where there is a sufficiently serious breach of the (above) obligations (other than the records requirement). But this would not affect the validity of rights already acquired under the arrangement; and
 - the power to give direction to commissioners to vary arrangements and tender procedures.

But (added by the revised version) Monitor may not direct a commissioner to hold a competitive tender for NHS healthcare services. (*Regulation 13 to 15*)

- **Damages actions.** Section 76(7) of the Act provides that a breach of any regulations made under section 75 of the Act is actionable. However, the NHS Procurement Regulations state that a person who has brought an action under the Public Contracts

Regulations for loss or damage may not bring an action under section 76(7) of the Act in respect of the whole or part of the same loss or damage. (*Regulation 17*)

This article comments on the implications of these provisions.

Do all NHS service arrangements now have to be tendered?

Position before the NHS Procurement Regulations

Under the Public Contracts Regulations 2006, healthcare services are classified as "Part B services" for which there are no formal procedural requirements as to whether, when and how to tender services. In particular, there is no obligation to publish an advertisement (contract notice) in the Official Journal of the European Union (OJEU) for Part B services.

NHS Trusts and other procurers of Part B services are required by Regulation 4(3) of the Public Contracts Regulations 2006, as amended to act in a transparent and non-discriminatory manner (where the contract is above threshold – currently £172,514). Commissioners will be subject to this requirement. Notably, this does not expressly require a tender to be conducted.

However, where a NHS 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 (see paragraphs 60-62, *Telaustria Verlags GmbH and Telefonadress GmbH v Telekom Austria AG (C-324/98) [2000]*). This requires an advertisement (the NHSCB website should suffice) and a non-discriminatory and transparent tender process.

EU principles are enforceable by a competing provider by way of an action under the Public Contracts Regulations (see Regulation 47A(1)(a)(ii)). Under current rules, therefore, Commissioners will need, in individual cases, to take a view on whether, if tendered, a particular contract might attract bids from non-UK providers and thus trigger EU law principles. Cross border interest may include interest from the UK subsidiary or branch of an international healthcare company (see *Deeny J in Federal Security Services Limited v Chief Constable of Northern Ireland [2009] NICH 3*).

Derogations

If EU law does apply, the tendering requirement is, however, subject to any applicable derogation or exception. For example, the specific exceptions set out in regulation 14 of the

Public Contracts Regulations should be available. These include the sole supplier and extreme urgency exception, but also for example the procurement of additional services in certain circumstances.

There are also specific exclusions to the Public Contracts Regulations (Regulation 8) which may be applied to any EU obligation to tender, notably where the provider has special or exclusive rights or, for example, where the primary nature of the contract is a land transaction (or a merger).

It may also be arguable that the protection of patient interests could provide a legitimate derogation from the application of the EU transparency requirement, particularly where the decision not to tender is necessary to preserve essential NHS services, such as A&E services. Article 106(2) of the Treaty on the Functioning of the European Union (TFEU) excludes the application of the Treaty rules to an undertaking entrusted with the operation of services of general economic interest, in so far as the prohibition would obstruct the performance in law or in fact of the particular task assigned to that undertaking. This exclusion has been invoked to justify the grant of exclusive rights to a provider of ambulance services, including non-emergency services which were necessary to protect the economic viability, quality and reliability of the core emergency services entrusted to the ambulance services provider. (See *Case C-475/99 Ambulanz Glöckner [2001] ECR 8089*.) However, that case related to the lawfulness of exclusive rights. No such rights have been conferred on NHS providers.

Position after the NHS Procurement Regulations

Regulation 3(2) of the NHS Procurement Regulations replicates Regulation 4(3) of the Public Contracts Regulations 2006 and in itself adds nothing to the existing position.

The provision in Regulation 5 of the NHS Procurement Regulations that no competition is required where there is only one capable supplier is based on the existing exception in Regulation 14(1)(a) of the Public Contracts Regulations. It does not state that it is the only exception to a duty to tender.

The NHS Procurement Regulations cannot and do not dis-apply EU requirements and exceptions. The position under EU law remains as before.

In fact, the words of the NHS Procurement Regulations are carefully chosen so that they do **not** impose a specific obligation to tender services. Commissioners must, under Regulation 3(3) of the NHS Procurement Regulations, procure the services from provider(s) most

capable of delivering their objectives (of securing patient needs, quality and efficiency) and providing best value for money. This may lead commissioners to conduct a tender designed to establish the best provider, but does not require a tender.

The non-exhaustive list in Regulation 3(4) of strategies that commissioners must consider to improve service quality and efficiency includes the option of enabling providers to compete to provide the services. Other options are service integration and enabling patient choice from a list of providers. This implies that while commissioners must consider the option of competing the contract, there is no specific duty to open the contract out to competition.

That implication is reinforced by the Department of Health (DH) notes which accompany the NHS Procurement Regulations. These state that regulation 3(4) "*enshrines the principle that it is for commissioners to decide how to improve the quality and efficiency of services*".

It follows that the NHS Procurement Regulations do **not** expand the application of procurement law to require all NHS healthcare service contracts to be advertised and tendered.

The new Regulations may, however, have this result in some circumstances.

First, there will be some situations where the commissioner has no choice but to procure in a manner which will secure patient choice between all capable providers. This is the case for non-urgent elective referrals in respect of the first outpatient appointment with a consultant under regulations 39 to 40 of the NHS Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 (SI 2012/2996) (this does not apply to cancer services, maternity or mental health). Regulation 7(3) of the NHS Procurement Regulations clarifies that commissioners must apply transparent criteria in qualifying providers and that the list of qualified providers must not be limited in number.

Second, the Regulation 3(3) duty to procure the services from the providers most capable of securing the needs of patients, improving service quality and improving efficiency and who provide best value for money imposes a specific and actionable duty on commissioners. When conducted properly, competitive tenders are an effective way of demonstrating that all reasonable steps have been taken to award the contract to the best bid. If, therefore, commissioners choose not to conduct a tender process they will need to have a convincing alternative basis for demonstrating that they have satisfied their duties.

In practice, even absent any possible cross border effect, this may lead commissioners to conclude that the prudent option is to conduct a tender in all but the most clear cut cases where there is only one capable provider.

Cost-benefit analysis

However, commissioners are reminded by Regulation 3 of their statutory duties of economy, effectiveness and efficiency (as well as that of promoting integration and proportionality). These must be weighed up to determine an appropriate procurement strategy and this must mean that a sensible cost benefit analysis should be 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. The statutory duties would then seem to point towards not tendering even where there is more than one capable provider.

Guidance on how commissioners should balance their duties and approach the decision of when to tender was published by Monitor in December 2013 (*Substantive guidance on the Procurement, Patient Choice and Competition Regulations*). By way of example, Monitor provides an expansive interpretation of the sole supplier exception at page 41. On Monitor's reasoning, that exception could be invoked where only the local Trust had the necessary infrastructure to supply A&E services and a critical mass of other services would then need to be co-located at the site for clinical reasons or reasons of commercial or practical viability. Monitor also stresses that it is for commissioners to decide whether and how to tender based on a balanced view of local circumstances, patient interests and the cost-benefit analysis.

The Guidance is indicative of the approach that Monitor might take in an investigation but would not bind the courts.

EU law trumps NHS Procurement Regulations

The commissioners' balancing exercise is, however, subject to the overriding EU requirement to go out to tender where there is cross border interest. By virtue of the sovereignty of EU law, this would trump the UK statutory duties.

Overall, the combination of duties under the Act and Regulations and the availability of derogations to EU tendering requirements point to an evolution towards competition rather than a liberalisation big bang.

The New Directive

Also of relevance are the provisions of the new Procurement Directive (2014/24/EU) which is to be implemented in the UK some time in 2015. Under Article 75, contracting authorities will have to publish a contract notice setting out their intention to award a healthcare services contract with a value of over €750,000. This ‘light touch régime’ is likely to make it clearer that large healthcare contracts will need to be competed unless a valid derogation is available.

Competition v Integration

The reissued Regulations nod to the perception that the issue is binary - either there is competition or there is integration - and lend more support to integration. This is seen in the added references to promoting integration in Regulation 2 and Regulation 3(5).

The binary view of competition and integration as opposing forces is misleading. In other sectors, there are many instances of integration, whether vertical (for example, between manufacturer and distributor) or horizontal (between competitors), structural (for example, merger) or behavioural which are compliant with competition law. Sometimes, they do not appreciably restrict competition, sometimes they create more competition than they restrict and other times the consumer or industry benefits outweigh any restrictions on competition.

In markets where there is a large public buyer, integration is often the end result of a competitive tender process. Competition and integration are often fairly comfortable bedfellows.

In ‘beefing up’ the references to integration, the revised Regulations do not therefore put a brake on competition. If, for example, the requirement is for a range of Community based integrated services, there may be a number of bidders or consortia of bidders able to deliver that requirement and interested in participating in a tender process.

The NHS Procurement Regulations also introduce new sector specific requirements relating to conflicts and level playing field.

Conflicts of interest

The rules on conflicts codify the application of principles of fairness and transparency to conflict situations. Given the dual role of GPs as commissioners and providers, conflicts are particularly likely in this sector. However, they feature in procurement in other sectors where there are, for example, in house bids and tender documents often provide for conflict resolution mechanisms. The publication of decisions and contracts is also in line with good public sector practice and legislation such as the Freedom of Information Act 2000.

Level playing field

There is a subtle but potentially important difference between the regulation 3(3) obligation in the NHS Procurement Regulations and regulation 4(3) of the Public Contracts Regulations. This is that under Regulation 3(2), commissioners must not treat a provider more favourably on the basis of its ownership. Monitor has conducted a Fair Playing Field Review and considered the need to neutralise some of the competitive distortions which result from, for example, differences in the application of corporation tax and VAT to NHS Trusts as compared to private providers or from access to NHS pensions, IT services and insurance. Regulation 3(2) is probably designed to combat direct discrimination in commissioning against either NHS Trusts or private providers, rather than introducing a general obligation to neutralise inequalities which arise from other sources. However, more specific guidance on this area would be helpful.

Monitor's enforcement powers

The grant to a sector specific regulator, Monitor, of powers to enforce procurement rules is novel. The NHS Procurement Regulations provide an alternative procurement dispute resolution mechanism to the courts. This may be attractive to disappointed bidders who have grievances but do not wish to invest in litigation.

Investigation

Guidance was issued by Monitor in December 2013 clarifying the procedures to be followed (*'Enforcement guidance on the Procurement, Patient Choice and Competition Regulations 2013'*). Monitor's powers are similar to equivalent powers under the Act (and the Competition Act 1998) to investigate competition infringements, though there is no express power to conduct surprise visits on premises (dawn raids). The effect of the power to require information is not dissimilar in practice to the disclosure process in litigation, though it will be Monitor rather than the challenger requiring the relevant documents. More specific guidance would be helpful as to the extent to which the challenger will be given access to Monitor's file.

Challenges

As Regulation 17 notes, section 76(7) of the Act makes failure to comply with a requirement of the NHS Procurement Regulations which causes loss or damage to be actionable (provided no claim for that damage has been made further to the Public Contracts Regulations 2006). Given the strict limitation periods applicable to challenges brought under the Public Contracts

Regulations 2006, a potential challenger will need to reach an early decision as to which route to follow. There are currently no limitation restrictions on the bringing of a complaint or action under the NHS Procurement Regulations (save those arising under general law applicable to a breach of statutory duty).

Damages

The NHS Procurement Regulations do not confer on Monitor the power to make a damages award and it may be inferred that, as with competition law, a 'follow on' action would need to be brought in the courts to recover damages, based on a favourable decision of Monitor made under the NHS Procurement Regulations. Guidance on this point from Monitor would be welcome. It should also be possible to bring an action directly in the courts to enforce the NHS Procurement Regulations and seek damages, which could be useful in circumstances where an action under the Public Contracts Regulations would be time barred.

Ineffectiveness declaration

Monitor's powers of decision under the NHS Procurement Regulations include the power to make a declaration of ineffectiveness. The power is wider than the equivalent power under the Public Contracts Regulations as the breach need only be "sufficiently serious". This contrasts, for example, with the rules in regulation 47K of the Public Contracts Regulations, which (under the second ground of ineffectiveness) requires there to be a breach of the standstill provisions. There is no reference in the NHS Procurement Regulations to the ineffectiveness being "prospective", though this may not matter in practice given the provisions in regulation 14(4) that there is no effect on rights accrued or liabilities incurred prior to the declaration. As no ineffectiveness declarations have yet been granted by the UK courts under the Public Contracts Regulations, this is uncharted territory.

Changes to remedies provisions

Finally, the reissued and final version of the NHS Procurement Regulations makes it clear that Monitor cannot instruct a commissioner to go out to tender. This may make little difference in practice.

If Monitor finds, for example, that a commissioner plans to enter into a contract without a tender with a provider who is not the most capable of delivering their objectives in relation to the required services further to Regulation 3(3), it may order the commissioner not to enter into that contract and to put in place measures to ensure compliance with the Regulations. Ultimately, the commissioner may be left with no choice but to go out to tender where there

are a number of interested, capable providers and the only sure means of choosing the best one is to conduct a tender.

Anti-competitive behaviour

The other significant area of novelty in the NHS Procurement Regulations is the rule that commissioners must not engage in anti-competitive behaviour which is against the interests of people who use health care services for the purpose of the NHS. Anti-competitive behaviour is defined in section 64(2) of the Act as behaviour which would or would be likely to prevent, distort or restrict competition. There is a further clarification in regulation 10(2) that there must be no restrictions that are not necessary for the attainment of intended outcomes which are beneficial for patients or other statutory objectives.

Contrast with current UK and EU law

This rule replicates a provision in the non-statutory Principles and Rules of Co-operation and Competition, which were applicable to the NHS and are effectively superseded by the NHS Procurement Regulations and requirements of the Act. There is, however, nothing quite like this in either UK competition or public procurement law. In EU competition law, Article 106(1) of the TFEU states that "*In the case of public undertakings and undertakings to which Member States grant special or exclusive rights, Member States shall neither enact nor maintain in force any measure contrary to the Treaty, in particular (the competition rules).*" This provision has been relied on by the European Commission to liberalise sectors such as telecommunications, but no such action is anticipated in healthcare. It seems unlikely that this provision would be invoked in a UK procurement dispute, not least because it would be difficult to show that providers had "special or exclusive rights".

The competition law prohibitions set out in the Competition Act 1998 are to be enforceable by Monitor as a concurrent regulator in the health care sector. However, these prohibitions only apply to the conduct and agreements of "*undertakings*". It is unlikely that commissioners, in the conduct of their NHS procurement functions, will be considered undertakings within the meaning of competition law. Guidance on the definition of an undertaking, based on EU case law, is set out in the Office of Fair Trading's December 2011 '*Public bodies and competition law - A guide to the application of the Competition Act 1998 (OFT1389) (December 2011)*'. This guide explains that where a public body buys goods or services for a public purpose and does not supply goods or services then it will not generally be acting as an undertaking (see *Case C-205/03, Federación Española de Empresas de Tecnología Sanitaria (FENIN)*).

The new rule in Regulation 10 therefore effectively stretches the scope of competition law to cover the commissioning of NHS healthcare services.

What conduct is caught?

Many cases of unjustifiable restrictions or distortions of competition brought about by commissioners would also breach principles of transparency and fairness (and other applicable procurement principles such as proportionality). This would cover, for example, any procurement activity which excludes certain bidders or classes of bidders from a tender or a choice framework or unjustifiably favours some bidders over others.

Further, the specific obligations on commissioners in Regulation 2 to act with a view to securing patient needs and improving service quality and efficiency could be interpreted to cover most other behaviour which might be deemed anti-competitive and contrary to patient interests.

However, the prohibition on anti-competitive behaviour is different as it introduces a competition based test. It provides a new mechanism for holding commissioners accountable and adds to their compliance burden. Commentators point to the need to regulate competition distortions which arise from procurement activity but fall outside the remit of competition law due to the undertakings test (see *Albert Sanchez Graells, Public Procurement and the EU Competition Rules (Hart Publishing, 1st ed, 2011)*). These include the aggregation of buyer power, the imposition of non-market standards, increased transaction costs, barriers to participation and risk of collusion.

Given that (in spite of the fragmentation of commissioning), the NHS is in effect a monopsony (a market with a single buyer), some of these competition concerns may be well-founded in this sector.

However, there are few clues in the Regulations as to what conduct will be prohibited. In its consultation document on the NHS Procurement Regulations, the DoH set out a number of possible examples of commissioner behaviour that could be caught by this prohibition (see *paragraphs 4.20 to 4.22 and figure 9, DoH: Securing Best Value of NHS Patients (15 August 2012)*). A number of these, such as joint purchasing and integrated or bundled care may, in individual cases, either not be restrictive of competition, have pro-competitive effects or be justifiable. Justifications could include the need to achieve economies of scale or scope to enable innovation and investment.

Perhaps more clear-cut examples of anti-competitive behaviour against patient interests could be where commissioners impose minimum waiting times (to save cost), agree exclusive arrangements, disclose commercially sensitive information or impose unreasonably onerous conditions of supply (such as very low prices) (see Monitor's *Substantive Guidance* at page 65). Further examples may be found in case-law on abuse of dominance (see, for example, *Arriva v Luton Operations* [2014] EWHC 64 (Ch)).

This prohibition could reduce tendering as there is an argument that unnecessary or over-formal tendering distorts competition by raising transaction costs. Equally, it seems possible that a decision by commissioners not to tender could be attacked as anti-competitive on the grounds that it unfairly favours the incumbent.

The interpretation of the prohibition is unpredictable. It also presents an added layer of complexity to commissioners at a time when they have a lot to do in just coping with their procurement obligations.

Monitor will, in time, make decisional practice on the prohibition and the courts will no doubt form their own view if faced with a claim based on breach of this provision.

New NHS procurement rules: conclusion

The new NHS Procurement Regulations provide some targeted rules on the specific objectives, considerations and practices that NHS commissioners will need to follow. They fall short of mandating that all new NHS service contracts save those which are specifically excluded should be put out to tender, though the practical effect of the various obligations (and indeed existing EU law) may be that many will or should be.

They give Monitor wide ranging powers to intervene and resolve disputes in the sector.

They introduce a novel obligation on commissioners, inspired by competition law, not to engage in anti-competitive behaviour that is against patient interests.

These rules present many challenges for commissioners. They do not effect a big bang requiring immediate liberalisation, but they are likely to subject commissioner activity to intense procurement and competition law scrutiny, with the prospect of intervention by Monitor to reverse decisions and damages actions being brought in the courts by disappointed bidders.

It seems inevitable that this will result in more competition between providers. Indeed, competition is likely to deliver greater patient choice, a key objective of the Act. Further, the

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protection of patient interests underpins all the new requirements and should provide a legal check on any liberalisation that threatens those interests.

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