Title: Procurement, Patient Choice and Competition Regulations (PCCRs) **Lead department or agency:** Department of Health **IA No:** 6083	**Impact Assessment (IA)** **Date:** 22/02/13 **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Secondary legislation

Summary: Intervention and Options

RPC Opinion: N/A

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, One-Out?**	**Measure qualifies as**
N/A	N/A	N/A	N/A	N/A

What is the problem under consideration? Why is government intervention necessary?

The Government is making regulations under Section 75 of Health and Social Care Act 2012 (HSCA) in order to maintain key existing requirements falling on Primary Care Trusts (PCTs) which are to be abolished. This includes establishing good procurement practice, protecting patient choice and addressing anti-competitive conduct where this acts against the interests of patients. This is necessary: 1) To set an appropriate framework of rules for commissioners to ensure value for money and protect patients' rights to choice without undermining their ability to secure services that meet patient need. 2) To ensure all relevant statutory/non-statutory requirements are mapped over to the new rules framework, giving Monitor an appropriate statutory enforcement role. 3) To establish a process for providers to seek redress, providing a credible alternative to seeking redress or damages through the courts.

What are the policy objectives and the intended effects?

A key aim of the HSCA was to empower commissioners to drive best quality, value and efficiency in the NHS. The regulations support commissioners to make rational and informed choices that maximise patient benefits and result in the most efficient long-term allocation of resources possible. The regulations also recognise that it may not always be clinically safe or economically efficient to prescribe more than one provider of a given service, especially where services are regulated, no other capable providers exist.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

1) Do nothing (EU & UK procurement law continue to apply to NHS commissioners, without the existing sector rules in health that apply to PCTs and with enforcement through the courts)

2) New principles and rules-based regulations supported by substantive guidance and with enforcement through a health sector regulator (preferred option).This option should allow commissioners sufficent freedom to improve health outcomes by using guiding principles to inform their decisions and by helping them act consistently with the law, while providing sufficent requirements for effective oversight.

3) New explicit rules-based regulations supported by minimal guidance and enforced through a health sector regulator.

Will the policy be reviewed? It will be reviewed as part of a wider evaluation of the effects of the health reforms. **To be commissioned in 2013/14**

Does implementation go beyond minimum EU requirements?			N/A			
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** No	**< 20** No	**Small** No	**Medium** No	**Large** No	
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** N/A		**Non-traded:** N/A	

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs.

Signed by the responsible Minister _____ Date: 22nd Feb 2013

Summary: Analysis & Evidence

Policy Option 2

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2013	PV Base Year 2013	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** N/A

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	N/A		N/A	**N/A**

Description and scale of key monetised costs by 'main affected groups'

There are negligible direct costs to patients, commissioners or providers. Monitor's costs in terms of enforcement capacity represents a transfer of functions from the Cooperation and Competition Panel (CCP). The CCP staff who previously advised on NHS specific procurement and competition rules (The Principles and Rules for Cooperation and Competition) will become an integral part of Monitor to carry out this enforcement function.

Other key non-monetised costs by 'main affected groups'

There could be indirect costs associated with commissioners' compliance with statutory provisions instead of non-statutory rules. This is difficult to estimate and could be negligible given that the requirements are broadly similar. The costs associated with clinical commissioning groups (CCGs) assuming commissioning functions from PCTs is quantified as part of the HSCA Impact Assessment.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	N/A		N/A	**N/A**

Description and scale of key monetised benefits by 'main affected groups'

Benefits of procurement best practice will include improved value for money which should underpin progressively higher quality services for the long term. Direct benefits will depend on the nature of individual enforcement cases and cannot be monetised. As an indicator of volume, CCP undertook six conduct or procurement cases under the PRCCs in 2011 and five in 2012. HMT sets targets for similar regulators (such as OFT) that enforcement intervention should yield a cost/benefit ratio of 5:1. The potential for dispute resolution through the courts will be lessened with associated cost benefits.

Other key non-monetised benefits by 'main affected groups'

The regulations strengthen patients' ability to choose by making statutory the enforcement of their rights to choice as set out in the NHS Constitution. Patients will also benefit from an effective enforcement mechanism to address potential conflicts of interest or anti-competitive behaviour that work against their interests.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

- Placing CCP within Monitor maintains the same approach to enforcement as at present;
- New commissioners will face the same commissioning challenges as those faced by PCTs (although they may approach securing local services differently, the processes will be the same); and
- Providers will use Monitor as the primary route for complaining and obtaining dispute resolution instead of the high up-front costs associated with the courts. (Spurious complaints will be mitigated by Monitor publishing prioritisation/acceptance criteria.)

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0	**Benefits:** 0	**Net:** 0	No	NA

Evidence Base (for summary sheets)

Problem under consideration

Consultation summary

The Department of Health (the Department) published an analytical narrative and call to evidence[1] to support its consultation document *Securing best value for NHS patients: Requirements for commissioners*. The response to the consultation was broadly supportive and the Department has moved towards implementation of the policy proposal.

The Department has published in full all the responses to the consultation exercise at: **http://www.dh.gov.uk/health/2013/02/consultation-responses-commissioners/**

Rationale for Intervention

It is broadly recognised that healthcare does not conform to the theoretical model of a well-functioning market. Broadly speaking, well functioning markets are those in which informed buyers and sellers interact and in which both buyers and sellers can enter and exit at low cost. Buyers make rational and informed choices in a way that maximises their wellbeing and results in the most 'efficient' allocation of resources.

There are many reasons why healthcare does not operate in the way described above. For example, there are fundamental information asymmetries for both commissioners and patients. It is also clear that "unfettered" competition in healthcare is unlikely to maximise patient welfare. There is a clear rationale for regulatory intervention to ensure that competition takes place within an appropriately governed framework with competition defined as a means to an end rather than an end in itself.

The previous Administration recognised the need to set rules to ensure that procurement and competition operate in the interests of securing best value services for patients. Since 2007, the Department has required Primary Care Trusts (PCTs) to comply with a set of administrative rules, the Principles and Rules for Cooperation and Competition, which include obligations to purchase services from the best providers, to protect patients' right to choice and to use procurement, competition and other tools effectively to improve services.

Since 2009, PCTs have also been required to comply with the *Procurement Guide for Commissioners of NHS Funded Services*, which includes more detailed requirements aimed at ensuring best practice in procurement. For example, it requires commissioners to engage with different providers and to hold open tendering processes where appropriate, so that they can compare providers and select the best possible services for patients.

[1] https://www.wp.dh.gov.uk/publications/files/2012/10/Annex_call-for-evidence.pdf

These rules and guidance are consistent with UK procurement law, which recognises that public bodies are not always under the same incentives to ensure best value. In particular:

1) Commissioners need to review continuously that the services they commission deliver best value for money for patients and taxpayers, rather than defaulting to existing contracts and providers.
2) Commissioners may have close working relationships with providers. This is certainly to be encouraged, for example to encourage innovation and new ways of working. However, commissioners should continue to ensure that the providers are delivering the best value for patients and for the taxpayer.
3) Commissioners may be under incentives to commission services from providers in which they have an interest as it helps to ensure financial balance or benefit but this may not always be in the best interests of patients and future patients.

The HSCA abolishes PCTs, establishes a new NHS Commissioning Board (NHS CB), and empowers clinical commissioning groups (CCGs) - the professionals closest to local patients - to commission the best services for their populations. Within these groups, GPs and other experts will use clinical insight and local knowledge to improve services. They will decide how to use resources, where to give patients more say over their care and treatment through greater choice, where to harness competition, and how to develop more integrated care.

The Principles and Rules for Cooperation and Competition apply only to the existing commissioners PCTs and, following their abolition, we will need to ensure the new commissioners continue to operate within a framework of sector-specific rules which enable them to secure the best quality services for patients. Those rules need to be accompanied by a proportionate enforcement mechanism in order to be effective.

Policy intention

We need to ensure these new commissioners continue to operate within a framework of sector-specific rules so that they secure the best services for patients that deliver best quality and that there is a proportionate enforcement mechanism in place.

The key policy intention is to:

1) **Set an appropriate framework of rules to raise standards in procurement practice by commissioners.**
2) **Make sure commissioners continue to act consistently with procurement and competition rules in the new system.**

3) **Protect the rights patients have to make choices under the NHS Constitution.**

4) **Provide Monitor with a proportionate enforcement role. This would be an alternative to enforcement through the courts.**

Commissioners will be responsible for the use of substantial public funds, approximately £80 billion. Appropriate standards of transparency and governance in decision-making need to be maintained and we need to ensure that commissioners can be held to account for their decisions.

For example, it is best commissioning practice always to carry out an objective assessment of different options and a rigorous evaluation of different providers. There is some evidence that this has not always been the case[2].

The Government has committed to providing commissioners with flexibility to decide how best to respond to the challenge of improving the quality of services for patients within finite resources, but commissioners need to be able to determine the services required to meet the needs of their populations. They must engage with patients and the public in developing commissioning plans for local services.

Commissioners can use a range of tools, including managing providers' performance, extending and varying contracts, widening choice of any qualified provider, and tendering. Local conditions vary and there is no one-size-fits-all model for raising standards.

Possible routes to secure services in the best interests of NHS patients can be categorised as below:

1. **Contract management (comparative regulation)** this tends to involve regulated core services where effective commissioning traditionally looks to build in ways to drive improvement in the absence of effective competition.
2. **Competition in the market** i.e. providing choices to patients so providers must compete to secure funding for healthcare services;
3. **Competition for the market (competitive tendering)** i.e. commissioners may look to exert competitive pressure on a range of providers in order to find the provider that can currently provide the best value and quality healthcare services.

[2] "Choice and Competition: A report from the NHS Future Forum", June 2011

The Counterfactual

The requirements of the existing Principles and Rules for Cooperation and Competition and the Department's procurement guidance provide a sector-specific framework for ensuring that PCTs work in patients' interests to deliver best value. These sector-specific rules also provide an alternative route to the courts for resolving procurement disputes.

However, PCTs are to be abolished and these non-statutory administrative rules would not be applicable to the new organisations taking responsibility for commissioning.

The Government has committed to retaining sector-specific rules for commissioners and to applying them through statutory arrangements (see the Government response to the NHS Future Forum report, CM 8113)[3] Failure to do so would be a step back, withdrawing important safeguards to protect patients' interests.

In the absence of a proportionate approach to resolving procurement disputes, commissioners will more likely be exposed to challenge through the courts. This could result in higher costs and delays to service improvements. Therefore, in the absence of the sector-specific regulations – Procurement, Patient choice and Competition Regulations (PCCR), the counterfactual would be that providers seek redress and damages through the courts under the Public Contract Regulations 2006.

The PCCR bring into one place requirements which are consistent with the existing requirements on commissioners, including UK Public Contract Regulations 2006 and EU law. These regulatory burdens would exist on commissioners absent of these proposed regulations, and commissioners absent of sector-specific rules may be faced with increased legal costs and disproportionate enforcement action through the courts.

[3] Earl Howe also "committed to retaining [the Principles and Rules] and giving a firmer statutory underpinning through Monitor's sectoral powers" during the Lords Debate on the Health and Social Care Bill on 13 December 2011 (Hansard, Column 1188, to be found at http://www.publications.parliament.uk/pa/ld201011/ldhansrd/text/111213-0002.htm#11121377000740)

Impact

Appraisal of broad options

Option 1: Do nothing

This would mean that the existing rules, requirements and guidance that apply to PCTs would cease to exist as the organisations are abolished. These non-statutory administrative rules would not be applicable to the new commissioning organisations which have greater freedom within a legislative framework and where the Secretary of State does not have powers of direction in relation to individual CCGs.

We would consider this to be a step backwards, removing safeguards for patients. For example, the protections in relation to patient choice, and prohibitions against anti-competitive behaviour that work against the interests of patients, would no longer be enforceable.

In addition, commissioners would potentially face higher costs associated with legal support services and compliance advice because the only regulations applicable would be non-sector specific public contract regulations with enforcement through the courts.

Option 2: New principles and rules-based regulations supported by substantive guidance (preferred option)

The preferred position, as consulted upon, is to retain the existing principles and rules, to which PCTs are required to comply and place them on a statutory footing through the PCCRs. This is consistent with the Government's response to the recommendations of the NHS Future Forum[4]. Monitor would enforce the rules and would have power to direct remedial action to address breaches of the regulations.

This option closely replicates the current position where a combination of rules and guidance aim to give commissioners greater flexibility than a purely rules-based approach (such as that set out in option 3), whilst ensuring that they can be held to account for their decisions.

This is the preferred option as it gives greatest flexibility to commissioners to decide how best to use tools such as integration, the extension of patient choice and competition as levers for improving services. It also gives greater scope to address any issues that have not yet been anticipated (via amended guidance).

[4] http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_127719.pdf

In developing option 2, we considered the impact of each requirement. The limited evidence available supported the retention and mapping of the existing principles and rules into regulation.

To mitigate against unnecessary compliance costs, commissioners will be supported by detailed guidance from Monitor on how to comply with the regulations and on the approach to enforcement action. This would be more proportionate than a one-size-fits-all approach which attempts to identify all potential harms prior to the conduct taking place. This could be overly bureaucratic, may not capture all future issues of conduct and could potentially constrain commissioners unnecessarily. The NHS CB also has a statutory role under the Act to support commissioners. The NHS CB will be publishing specific guidance related to the regulations, for example on procurement practice and the management of conflicts of interest.

This approach is intended to give commissioners greater confidence in taking decisions and allows for guidance to be updated from time to time to reflect lessons learnt and promote developments in good practice.

Mapping individual principles and rules under the preferred option

The Department has designed the individual requirements on procurement, patient choice, anti-competitive behaviour and conflicts of interest to be consistent with our preferred approach (option 2).

Procurement

Competitive tendering

Regulation 5 of the PCCRs makes clear that it is not the intention of the Department to mandate that commissioners should competitively tender all contracts. There are often very valid technical reasons in healthcare, whether it is for clinical safety, expediency or investment in innovative new clinical services that there is only one capable provider of services. To require tendering in these areas would incur unnecessary costs to the NHS, unnecessary delay and potentially yield little gain. Regulation 5(2) outlines these specific circumstances where competitive tendering is not required in line with UK procurement law.

Transparency

During consultation the importance of transparency in procurement was highlighted. At present the Department's procurement guidance requires all qualifying advertisements and invitations to tender to be placed on the website *Supply2Health.* The regulations require commissioners to maintain records of their decisions and publish details of the contracts they have awarded on a website maintained by the NHS CB and provide for this to be enforced. This is consistent with the Department's existing procurement guidance and wider Cabinet Office guidance linked to the Government's open public services agenda.

In the absence of any significant concerns that the proposals on the procurement rules in the PCCRs would present a net cost to commissioners, we have designed the regulations in line with the preferred overall option.

Anti-competitive behaviour rules

The regulations continue the approach under the existing Principles and Rules for Cooperation and Competition whereby an 'effects-based' approach is taken in assessing whether particular conduct operates for or against patients' interests. We recognise that there are circumstances where commissioners might legitimately seek to restrict competition, for example, where this is necessary to ensure that individual providers achieve minimum volumes of surgical procedures for reasons of patient safety.

Patient choice rules

The responses to the consultation and call to evidence were light on specific examples of potential impact but were broadly supportive of the proposed approach to protect the rights patients have to exercise choice under the NHS Constitution, including the right in relation to choice of secondary care provider.

There are no additional requirements placed on commissioners in relation to patient rights to choice. The regulations provide for enforcement of these rights on a statutory footing.

Conflicts of interest rules

The conflict of interest rules were designed in light of the consultation responses and call to evidence. The regulations build on the existing requirements in the Department's procurement guide for managing conflicts. They provide Monitor with powers to investigate where conflicts have influenced, or appear to have influenced, commissioning decisions.

The Government recognises that the accompanying guidance to support commissioners in complying with these regulations will be very important for reducing compliance costs.

Commissioners' behaviour

Under the preferred option, the existing principles and rules would be retained and placed on a statutory footing. There could potentially be a behavioural change by commissioners in response to a statutory rather than non-statutory set of rules. The cost of this is difficult to quantify but is unlikely to represent a significant change given the continuity of approach taken under option 2.

Guidance will also have an impact on behaviour. NHS CB and Monitor will produce guidance to support commissioners in complying with the PCCRs, and this is expected to reduce compliance costs associated with the PCCRs.

Potential benefits of a statutory regime include a reduction of inefficient and non-compliant conduct, realising increased benefits to the system as a whole.

Option 3: New prescriptive rules-based approach supported by minimal guidance

While option 2 is the preferred policy option, an alternative approach of producing new, detailed regulations relating to actual conduct by commissioners has also been considered. The approach would bring greater clarity for commissioners as to the explicit obligations on them, as well as clarity on the costs associated with compliance. This may reduce the extent to which more detailed guidance was required, but would significantly reduce the level of flexibility for commissioners.

There are certain disadvantages to this approach. Firstly, it is anticipated that the compliance costs associated with this approach may be higher, especially in the short term. Although commissioners would have more certainty, they would also be relatively unfamiliar with this approach and one of the main benefits of the preferred option is that it is very similar to the current rules, requirements and guidance, but places this on a statutory footing.

It is also difficult, in practice, to draft more specific rules of this kind without increasing the risk of unintended consequences. This has the effect of reducing the flexibility available to commissioners to act to improve services for their patients. For example, a more rules-based approach might specify a “blacklist” of anti-competitive behaviours. However, in most scenarios discussed during our engagement with stakeholders, there was at least some scope for most behaviours to be justified in particular circumstances on a case by case basis. For example, patients could potentially benefit from action taken to limit the number of providers competing for a service if doing so ensured efficient and sustainable provision of services.

There is also risk, when placing rules on a statutory footing, that specific conduct rules would create unhelpful case law that in time was found set to rigid presidents for the regulator and would be difficult to move away from without changes to legislation.

This approach therefore risks being too rigid and, in contrast, an approach relying on principles where the effect of commissioning decisions must be proved (as in option 2) has the potential to be the most flexible and cost-effective option.

Specific impacts

System Transition

The Department recognises the regulations need to be sensitive to the transitional issues that may arise because of annual contract terms being agreed in respect of certain services prior to 2013/14.

These arrangements need to be distinguished from normal contracting rounds. The Government has therefore provided in the PCCRs that contracts transferred by Secretary of State and Strategic Health Authorities or PCTs will not be considered as new contracts for the purposes of Regulation 5.

Small and Medium Enterprises (SMEs)

Small and medium size organisations should benefit from greater transparency in commissioning and fairer, more proportionate procurement. They will also benefit from a more certain approach to enforcement.

SMEs and the third sector organisations would be better able to raise complaints, where appropriate, to Monitor to address procurement issues and other potential breaches. The third sector in particular has raised concerns that, to date, many smaller providers have not had the resources to challenge poor commissioning through the courts.

Conclusion

Summary and preferred option

The Department has concluded after considering the response to the consultation to continue with a broad principles approach supported by specific guidance published by the NHS CB and Monitor. This impact assessment has explored some of the specific impacts that could result from the implementation of this approach.

In general, it is difficult to quantify any net costs associated with the preferred option. The counterfactual option, where existing rules would be unenforceable, could represent higher net costs (although we have not considered them directly). Moreover, the benefits of the preferred option are potentially high, and the Department is confident that there will be an indirect net gain to commissioners and to the quality of services offered to patients.

Implementation and evaluation

The Department has stated its intentions to monitor the implementation of its policies. The previous administration commissioned an independent evaluation of the impact of many of its policies on the NHS, and during

2013/14 the Department of Health will commission a similar evaluation programme.

The Department will also be working with Monitor and the NHS CB to produce guidance on compliance with, and enforcement of, the regulations in 2013.