Securing the Best Value for Patients

Consultation Response Document

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1. Introduction

1.1 The reforms introduced by the Health and Social Care Act 2012 (the Act) place patients at the heart of the NHS and lay the basis for a health service which achieves world-class outcomes – one which provides better information, offers patients more involvement and greater choice, develops more responsive services and delivers higher safety, quality and value for money.

1.2 The Act establishes the NHS Commissioning Board (the Board) and Clinical Commissioning Groups (CCGs) - the professionals closest to local patients - to commission the best services for their populations. The Board and CCGs will be responsible for securing best value for NHS patients through their control of over £80 billion of annual public expenditure.

1.3 The Government has protected the NHS budget and is continuing to increase it in real terms. Nevertheless, given the current fiscal situation, the NHS is facing one of the tightest funding settlements in its history. Commissioners will need to use their finite funding as effectively as possible in responding to growing pressure on services.

1.4 We therefore need to ensure that commissioners operate within a framework of rules so that they secure the best clinical services for patients and deliver best value.

1.5 The Department of Health consulted on proposals for regulations that would provide this framework for commissioners with oversight from the independent health sector regulator Monitor. The consultation document, "*Securing Best Value for NHS Patients*", was published in August and the consultation closed on the 26th October 2012. This document summarises the main findings and conclusions from the consultation and explains the approach the Department has taken in developing the regulations.

2. Consultation Process

2.1 During the consultation period, the Department undertook a series of meetings, workshops, webinars and discussions with commissioners, providers and a range of stakeholders and representative organisations. This followed earlier engagement in advance of the publication of the consultation document and its proposals.

2.2 The consultation document invited responses to 10 questions about the proposals. The Department received over 80 responses to the consultation from a range of individuals and organisations. A full list of respondents can be found at Annex A. The responses have been published alongside this document on the Department's website (http://www.dh.gov.uk/).

2.3 The Department has continued to work closely with the Board and Monitor in developing the regulations, taking into account the issues raised during the consultation.

2.4 We would like to thank all those who took the time to respond to the consultation.

3. Responses to the consultation

3.1 The responses to the consultation demonstrated broad support, across a wide spectrum of stakeholders, for the proposals to use the regulations to set broad principle based requirements for commissioners when procuring and contracting for services to safeguard the interests of patients.

3.2 For example, the NHS Confederation was *''supportive of the approach adopted in the guidance to establish broad principles for good procurement practice in the regulations.''* Similarly the Royal College of GPs stated that they ''*really welcome the approach taken overall'',* going on to say, *''in the main, we feel this is a very constructive document, reflecting many of the improvements brought into the Health and Social Care Bill during its passage.''*

3.3 Almost all those who responded agreed that the rights of patients to make choices, as enshrined in the NHS Constitution, should be protected but that choices beyond these would be a matter for individual CCGs supported by the Board, or for the Board itself, consistent with the objectives of the Mandate. For example the Foundation Trust Network stated that *''it seems sensible that the proposed regulations should cross reference and safeguard existing rights under the NHS Constitution.''* The British Medical Association (BMA) commented that ''*The regulations should not impose additional requirements on commissioners over and above the rights to choice set out in the NHS Constitution. Local commissioners are best placed to take the lead in deciding where and how to extend patient choice and the regulations must not act as a barrier to this.''*

3.4 There was also broad support for the approach proposed on anticompetitive behaviour whereby restrictions on competition would be balanced against any patient benefits, building on the approach under the existing Principles and Rules for Cooperation and Competition.

3.5 We have, therefore, on the whole, looked to continue the approach set out in the consultation.

3.6 However, of particular concern to respondents was the potential for conflicts of interest in the new system and the need to ensure that conflicts, or potential conflicts, of interest in procurement decisions can be adequately addressed. We have, therefore, looked to strengthen Monitor's power to act where conflicts or potential conflicts may affect the integrity of a commissioner's decision to award a contract.

3.7 We also heard that the accompanying guidance to support commissioners in complying with the regulations will be very important.

3.8 The following sections set out the key points raised in response to the questions asked during the consultation and how the Government has responded.

4. Ensuring good procurement practice

4.1 The over-arching intention of the procurement requirements set out in the consultation was to focus commissioners on securing high quality services for their populations and ensure commissioners are accountable for their decisions.

4.2 We proposed high-level requirements for commissioners to ensure their decisions on expenditure for clinical services are transparent, proportionate, non-discriminatory and always objectively justified.

4.3 The following response was received to the consultation questions:

Q1. Do you agree that we should establish broad principles for good procurement practice in the regulations, rather than setting more prescriptive procedural rules?

***Yes* 80%** ***No* 8%** ***N/A* 12%**

We also asked the following questions:

Q2. Do we need to introduce any additional safeguards to ensure that commissioners comply with good procurement practice?

Q3. Could the proposals have any perceived or potential impact on equality including people sharing protected characteristics under the Equality Act 2010?

4.4 Most respondents, around 80%, were supportive of the Government's proposed approach to set broad principles of good procurement rather than more prescriptive rules, with a view to retaining flexibility for commissioners.

4.5 Many respondents suggested a prescriptive approach was unlikely to be beneficial. For example, the NHS Confederation stated that it *'is supportive of the approach adopted in the guidance to establish broad principles for good procurement practice in the regulations. Setting rigidly prescriptive rules would not support the Government's policy of devolving freedoms and flexibilities to allow commissioners to work with providers to secure the best outcomes for patients. Underpinning the principles with guidance from the Board regarding their implementation seems like a sensible approach as it will enable commissioners to retain their autonomy and flexibility and apply the principles in a manner to best suit their local circumstances, while providing some consistency regarding their interpretation.''*

4.6 Social Enterprise UK, whose views were typical of those received felt that *"procedural rules that are too prescriptive could limit commissioners' ability to support innovation.''*

4.7 Based on the consensus we have heard, we will continue to take forward a principles-based approach in drafting the regulations.

4.8 A broad range of views were expressed on the question of further safeguards to protect patients' and taxpayers' interests. Many suggestions related to the management of conflicts of interest (which is considered further in the chapter on conflicts), or the need for guidance and support for commissioners. Key themes and our response are set out below.

Commissioners decide

4.9 The starting principle for our proposals was that it is for commissioners to decide how best to secure services for their populations and that they should have a broad range of options. Many respondents, including the Royal College of GPs, strongly endorsed this principle. We will therefore seek to enshrine this principle in the regulations.

Sustainability

4.10 Several of those responding made reference to either the Public Services (Social Value) Act or to the need for commissioners to have regard to the sustainability of services as required by the existing Principles and Rules for Cooperation and Competition. Representatives of the NHS Social Partnership Forum set out in their response that *''The trade union side is concerned that the requirement to have regard to the sustainability of services, included in the current wording of Rule 1 of the Principles and Rules for Cooperation and Competition, has been excluded.''*

4.11 We agree that issues of social value and sustainability will be important for commissioners to consider in taking their decisions. The requirements of the Social Value Act will apply to commissioners by law from the 31 January 2013 and, therefore, it is not necessary to duplicate these requirements in the regulations.

4.12 The Department is not proposing to include a specific requirement in the regulations for commissioners to have regard to the sustainability of services over and above other important considerations such as patient safety, access to care, improving quality or enabling the delivery of integrated services.

4.13 Sustainability is one of many relevant considerations that commissioners will need to balance in coming to their decisions. Given this, and while the Department acknowledges the importance of this issue, we consider it would be more appropriate for considerations in relation to the sustainability of services to be set out in the Board's procurement guidance to commissioners. For example, sustainability will be an important consideration for commissioners in making decisions on contract terms, contract duration and in thinking about whether services should be bundled together to enable integration or to allow patients to benefit from economies of scale and scope.

Guidance

4.14 A strong theme from respondents was the recognition that CCGs are developing organisations and will need support and guidance on procurement issues, including,

case studies, toolkits and practical help where appropriate. There were calls for Monitor and the Board to work together to provide such support.

4.15 Monitor and the Board will be working together to decide how best to support commissioners with guidance, including on procurement, in 2013. Monitor has a duty to publish guidance for commissioners on compliance with the regulations. The Board will also publish guidance in early 2013 to help CCGs understand and work within the Regulations, including in relation to conflicts of interest. The Board and Monitor are working closely together so that their guidance is consistent and will bring the guidance together through a resource for the NHS called the Choice and Competition Framework.

4.16 There are two further issues where we have updated our proposals

- We had proposed that commissioners be required to publish the details (eg scope of services, contract value) of all contracts they had entered into for the provision of healthcare with a value of over £10,000. After further consideration, and in light of views on the importance of accountability and transparency, we do not intend applying a *de minimis* threshold to this requirement.

- We had also proposed that commissioners must act proportionately and had highlighted a specific instance of disproportionate behaviour that can occur if providers are required by commissioners to duplicate requirements imposed by registration or licensing. We still consider that such unnecessary burdens on providers must be prevented but, on balance, consider creating a requirement with such wide scope may lead to unforseen consequences. Therefore, we believe it appropriate for specific examples of behaviour that may be disproportionate to be set out in guidance.

Impact on equality

4.17 There were few responses that highlighted any perceived impact or potential impact the proposals would have on people sharing protected characteristics under the Equality Act 2010. One of the few comments that were received noted the duties commissioners already have in relation to equality under existing legislation, including the Equality Act 2010. Given that commissioners already have strong duties as set out in primary legislation, including to advance equality of opportunity between people who share a protected characteristic and people who do not, we do not intend to introduced further requirements to be enforced by Monitor.

5. Protecting patients' rights to make choices

5.1 The consultation proposed that the regulations should be used to protect the rights that patients have to exercise choice, as set out in the NHS Constitution but would not place additional requirements on commissioners to extend patient choice. This was in order to retain flexibility for commissioners, who are best placed to take the lead in deciding where and how to extend choice in individual local services supported by the Board.

5.2 The following response was received to the consultation questions:

Q4. Do you agree that the regulations should protect patients' rights to exercise choice as set out in the NHS Constitution?

***Yes* 73%** ***No* 4%** ***N/A* 23%**

We also asked the following question:

Q5. Are there any further safeguards that should be established through the regulations or elsewhere to protect the extension of choice?

5.3 On the whole, the consultation revealed broad support for the proposal to protect the existing right patients have to choice under the NHS Constitution but not to introduce further requirements through the regulations in relation to the extension of patient choice.

5.4 The Patients Association, for example, said that *"We agree that there should be regulations to protect patients' rights to exercise choice as set out in the NHS Constitution. We are encouraged to see the focus on the NHS Constitution here and look forward to seeing it being used elsewhere."*

5.5 The Royal College of GPs responded to say that *"We recognise, given the structural changes there will need to be a mechanism to ensure that the existing right to exercise choice contained in the NHS Constitution are consistently adhered to across the NHS."*

5.6 In terms of further safeguards to protect the extension of choice, many respondents recommend that local commissioners needed to be free to take these decisions. For example, the Foundation Trust Network responded to say that, *"we would not advocate additional, legislative safeguards at the current time"* and the BMA recommended that, *"Local commissioners are best placed to take the lead in deciding where and how to extend patient choice and the regulations must not act as a barrier to this."*

5.7 There were a number of other specific suggestions regarding further safeguards outside of the regulations to protect the extension of choice, the most frequently expressed of which was the need for more guidance from the Board to CCGs. For example, the NHS Confederation recommended that *"Rather than including additional safeguards within*

the regulations we believe that the most effective way to help promote the extension of choice, where appropriate, is to support commissioners in delivering the choice agenda by providing evidence, guidance and good practice examples on how best to utilise competition and to help patients with exercising their right to choice of provider and type of treatment." We have already taken action on this point and set objectives for the Board in the first Mandate to support CCGs to ensure that patient rights to make choices are fully embedded and that patient choice is extended.

5.8 Other recommendations on safeguards included calls from the NHS Partners Network for an evaluation mechanism (data collection) to see how patient choice is being implemented. The Department will be asking Monitor to consider how best this could be taken forward.

5.9 We also heard that patient choice is much wider than just a choice of who provides the service and that patients need to be supported with appropriate information if choice is to be meaningful. As one respondent put it, the combination of proposed regulations and the Monitor licence conditions in this area should be adequate, but there is also a significant amount of work required in relation to patient education and information in order to support well informed choices.

5.10 Given the views expressed during the consultation, we have continued to take forward the balance of our proposals in drafting the regulations.

6. Preventing anti-competitive behaviour against patients' interests

6.1 The consultation set out the Government's view that competition is not an end in itself, but one of the tools that can be used by commissioners to drive up standards and achieve world-class outcomes.

6.2 We therefore want to ensure competition is effective in strengthening incentives for providers to improve services. We want to ensure that where providers compete, they do so on equal terms and that the best providers succeed. We therefore need to ensure that behaviour that restricts competition that is against the interests of patients or the taxpayer because, for example, it allows providers to maintain lower standards of care, is prohibited. Examples include a commissioner unfairly excluding a provider from applying to deliver services to patients, even where this could lead to better quality or more efficient services being provided to patients, or a commissioner including provisions in contracts with providers which limit their ability to compete with each other on quality, such as by imposing minimum waiting times not based on clinical need.

6.3 In addressing anticompetitive behaviour, we proposed to continue the existing approach under the Principles and Rules for Cooperation and Competition and maintain an 'effects based' approach to assessing whether particular behaviour operates for or against patients' interests. This recognises that there are circumstances where commissioners might legitimately seek to restrict competition where this would be in patients' overall best interests, for example, where this is necessary to ensure that individual providers achieve minimum volumes of surgical procedures to ensure patient safety.

6.4 We proposed that, like the Principles and Rules, there would be a broad prohibition of behaviour that restricts competition against the interests of patients rather than a specific list of behaviours that are prohibited in all circumstances. This reflected the difficulty in prohibiting specific behaviour *per se* as the behaviour may not always be against the interests of patients.

6.5 The following response was received to the consultation questions:

Q6. Do you agree that we should adopt an effects based approach to assessing restrictive conduct by commissioners, rather than assuming that conduct which restricts competition is automatically against patients' interests?

***Yes* 64%** ***No* 4%** ***N/A* 32%**

We also asked the following questions:

Q7. What can the Department of Health, Board and Monitor do to ensure that commissioners understand the requirements so that they can effectively 'self-assess' whether or not their conduct falls within the rules?

Q8. Are there particularly problematic behaviours which we should address specifically, for example in the requirements or in Monitor's guidance for commissioners?

6.6 There was support for an effects based approach proposed whereby restrictions on competition would be balanced against any patient benefits, and a general acknowledgement that competition is not an end in itself but rather that it is a tool for driving up quality.

6.7 For example the Social Partnership Forum stated that *''We agree that the "effects-based" approach to assessing whether particular conduct operates for or against patients' interests (paragraphs 4.11-4.13) is preferable to the blanket assumption that any conduct that restricts competition is automatically bad for patients.''*

6.8 The BMA also responded and stated that *''We agree that an effects based approach should be adopted, to ensure a greater degree of flexibility for commissioners.''*

6.9 Others, such as the Confederation of British Industry and the NHS Partners Network, recommended that in investigating possible anticompetitive behaviour there should be *''a presumption that conduct which serves to restrict competition is usually going to be against patients' interests.''*

6.10 In general, there was a call for greater guidance for commissioners, including evidence that commissioners could access, a library of examples and case studies that would make clear why particular behaviour in particular circumstances would be likely to be deemed anti-competitive. There were also calls for Monitor and the Board to help commissioners to identify which types of behaviour could be deemed to be anti-competitive.

6.11 We agree. Monitor and the Board are working together to produce a joint Choice and Competition Framework which will provide a resource for commissioners and providers considering matters relating to competition. Monitor will also be consulting on its guidance on compliance with these regulations and its approach to enforcement in due course.

The relationship between procurement and anticompetitive behaviour provisions

6.12 An issue that emerged during the consultation was the relationship between the requirement prohibiting anticompetitive behaviour and the procurement requirements. For example, the Royal College of GPs sought reassurance that the anticompetitive behaviour provision is *''not principally directed at decisions on whether to tender.''* This reflects continuing concerns by some stakeholders that in practice Monitor might use its powers to promote competition for competition's sake.

6.13 During the passage of the Health and Social Care Act 2012, the Government amended Monitor's duties so that its primary duty is to protect and promote the interests of people who use healthcare services. Monitor's role in relation to competition is not to 'promote competition' but to prevent anticompetitive behaviour which is against the interests of patients.

6.14 As set out during the consultation, it would not be Monitor's role under the regulations to direct where commissioners should introduce competition or patient choice of any qualified provider locally.

6.15 As required by the regulations, when procuring services commissioners will need to ensure that they act with a view to securing the needs of patients and improving the quality and efficiency of services. Monitor's role is to investigate whether commissioners have respected due process, considered the full range of options and made objective decisions on how to commission services in patients' best interests.

6.16 Where a commissioner has taken a decision that is compliant with the procurement requirements in the regulations and that is in patients' interests then neither the Department nor Monitor would consider this in breach of the requirement prohibiting anticompetitive behaviour. Monitor will make this clear through guidance.

The indispensability test

6.17 Of concern to some respondents was the proposed ''indispensability test''. This stated that ''restrictions to competition will not be in the interests of people who use healthcare services unless they are indispensable to the attainment of the intended benefits for people who use these services.''

6.18 The policy intention was to require a commissioner to be able to demonstrate that a restriction on competition was a necessary and proportionate means to deliver the intended benefits to patients.

6.19 There were a number of calls for more clarity around the types of behaviour that would be caught by this proposal. For example, the BMA considered that *''this is a broad term that could be open to interpretation''* and recommended that *''some tightening of the wording or guidance may be necessary.''* Some considered the language of 'indispensable' too strict a test.

6.20 However, others were supportive, for example the Office of Fair Trading stated that it *''considers that an indispensability test is an appropriate filter through which to judge whether patient benefits enable a commissioning body to justify anti-competitive behaviour.''*

6.21 In view of this, in taking forward the regulations we intend to require that arrangements 'must not include any restrictions on competition that are not necessary to achieve intended outcomes which are beneficial for patients'. We consider that it is important

that restrictions on competition that are not necessary to achieve benefits are prohibited, but we think that the language of necessity is more widely understood than the language of indispensability.

6.22 We also agree that guidance will be needed for commissioners to help support them in understanding the application of this test and as set out above further guidance will be issued for consultation in due course.

7. Managing conflicts of interest

7.1 Our proposals set out an important role for the regulations and Monitor to address conflicts of interest. We had proposed not to duplicate the governance/organisational requirements already provided for in the Health and Social Care Act but to complement these by allowing action to be taken in individual cases where the decision to award a contract was the result of an interest in the provider.

7.2 The following response was received to the consultation questions:

Q9. Do you agree that the Act and proposed requirements impose sufficient safeguards to ensure commissioners manage Conflict of Interest appropriately?

***Yes* 34%** ***No* 35%** ***N/A* 31%**

The following question was also asked:

Q10. If not, what additional safeguards could we introduce?

7.3 Concern about the potential for conflicts of interest under the new arrangements, with GPs having an interest in both commissioning and provision, remained a significant issue for many respondents. Around half of those that commented on Q9&10 recommended that further action be taken to address conflicts.

7.4 The BMA commented that, *"It is essential that there are no conflicts of interest that are obscured from scrutiny. There will inevitably be matters where the CCG board or members have a pecuniary interest but these should be handled in a way that ensures probity. Commissioners will need to withstand any scrutiny and answer for any deficiencies. Perceived conflict means there IS a conflict of interest."*

7.5 Suggestions around what more could or should be done in this area included further guidance and examples of best practice, clarification of Monitor's and the Board's roles, and some proposals around policing and managing potential conflicts, for example through a role for external reference groups. These suggestions also included being more explicit about the level of detail that must be recorded on how decisions have been made where a conflict of interest has been identified. Suggestions for measures to manage circumstances where CCG members have interests in a provider ranged from declaring that interest, to being prevented from playing any part in the decision making process.

7.6 We consider that guidance from the Board and the implementation of the requirements of the Act by CCGs already provide the framework for addressing many of the concerns raised while allowing commissioners flexibility to put in place processes that meet varying local circumstances.

7.7 However, given the views expressed on this issue, we want to ensure that there is a strong requirement in place through the regulations to safeguard the interests of patients and the taxpayer and that Monitor has sufficient scope to be able to take action in individual cases.

7.8 We will, therefore, strengthen the requirement to prohibit a commissioner from awarding a contract where conflicts, or potential conflicts, between the interests involved in commissioning such services and the interests involved in providing them affect, or appear to affect, the integrity of the award of the contract.

7.9 This will provide a stronger safeguard to protect patients' and taxpayers' interests and mean that Monitor is able to take action where conflicts have not been managed appropriately in awarding a contract, and not only where Monitor is able to establish that the decision to award a contract to a provider was the result of an interest in the provider – which may have set too high a bar to allow action to be taken.

7.10 Finally, we consulted on a proposal to require commissioners to record where a provider also appears in their register of interests. However, we are not pursuing this through the regulations as, after further consideration, we consider this would create unnecessary duplication and bureaucracy.

8. Next Steps

8.1 The Department would like to thank all those who took the time to respond to the consultation.

8.2 The regulations will shortly be laid before parliament to come into force from 1 April 2013.

8.3 Monitor will be consulting on its guidance for commissioners on the regulations in the coming months.

Annex A – list of organisations who responded

Members of the public who responded on an individual basis have not been listed below.

- Bevan Brittan LLP
- British Acupuncture Council
- British Generic Manufacturers Association
- British Medical Association (BMA)
- Business Services Association
- College of Occupational Therapists
- Coloplast
- Community Action Hampshire
- Confederation of British Industry (CBI)
- Coventry Local Involvement Network (LINk)
- Darlington Borough Councils Health and Partnership Scrutiny Committee
- Dorset Local Pharmaceutical Committee
- English Community Care Association
- Expert Patients Programme Community Interest Company
- Foundation Trust Network (FTN)
- Great Western Hospitals NHS Foundation Trust
- Guild of Healthcare Pharmacists
- Independent Mental Health Services Alliance
- InHealth Group Limited
- Lesbian & Gay Foundation
- Londonwide Local Medical Committees (LMCs)
- Macmillan Cancer Support
- Marie Stopes International
- Medical Protection Society
- Midlands and East Specialised Commissioning Group
- National Association for Voluntary & Community Action (NAVCA)
- National Clinical Homecare Association
- National LGB&T Partnership
- Neurological Commissioning Support
- Newlife Foundation for Disabled Children
- NHS Confederation
- NHS North of England
- NHS Partners Network - NHS Confederation
- NHS Protect
- NHS SBS Commercial Procurement Solutions
- NHS South West London / NHS Kent & Medway / KSS Deanery
- NHS Social Partnership Forum's Staff Passport Group (BMA, CSP, MiP, RCN, UNISON, Unite)
- NHS Sustainable Development Unit
- Nuffield Health
- Office of Fair Trading
- Optical Confederation
- Parliamentary and Health Service Ombudsman
- Patients Association

- Pharmaceutical Services Negotiating Committee
- Pharmacy Voice
- Primary Care Foundation
- Priory Group
- Regional Voices
- Royal College of General Practitioners
- Royal College of Midwives
- Royal College of Nursing
- Royal College of Psychiatrists
- Royal College of Radiologists
- Royal Pharmaceutical Society
- Shropshire Patients Group – Patient Voice
- Social Enterprise UK
- St John Ambulance NHQ
- Stockport Health & Care Forum
- Sue Ryder
- Tees, Esk and Wear Valleys NHS Foundation Trust
- The Practice
- United Kingdom Accreditation Service
- Urology Trade Association
- Virgin Care Limited
- Walsall CCG
- Weight Watchers
- West Berkshire LINk & Chair SELLNet
- Worcestershire County Council - Mental Health team

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