Lords Debate on Motion to Annul Section 75 Regulations
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The British Medical Association (BMA) is an independent trade union and voluntary professional association which represents doctors from all branches of medicine across the UK. It has a total membership of over 151,000.

The BMA is calling for withdrawal of the National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations. We believe that they should be replaced with new regulations unambiguously reflecting prior Government assurances that commissioners will not be forced to use competition. This principle should be stated explicitly in the regulations.

Overview

During the legislative stages of the Health and Social Act 2012 (the Act), the BMA raised serious concerns about the Government’s intentions to increase use of competition in the National Health Service (NHS) in England.

The BMA successfully called for the removal of clauses in the initial version of the legislation that would have allowed providers to compete for contracts on price, highlighting the decline in quality associated with price competition.

Following the legislative pause and the work of the NHS Future Forum, further clauses in the Act ensured that the sector regulator, Monitor, cannot act with the intention of causing variation in the proportion of NHS health care services that are delivered by public or private sector providers. We also pressed successfully for amendments to the legislation to limit some of its most damaging aspects, including changes to proposals requiring Monitor to promote competition. This resulted in a corresponding change to its main duty to one of protecting and promoting the interests of people who use health services by promoting services which are economic, efficient and effective.

Since the Act received Royal Assent in 2012, we have maintained our opposition to increased competition and the development of the market in the NHS, whilst also working to mitigate further the worst aspects of the new system. Statutory Instruments No. 257¹ laid before Parliament on 13 February 2013 provided details about how aspects of patient choice and competition would operate under the Act from 1 April 2013. The regulations were intended to ensure good procurement practice, but prompted widespread concern and uncertainty about the apparent
requirement for commissioners to advertise competitive tenders for most health services. Ministers have refuted this interpretation (see section on Government assurances on pages 5-6) but this is not adequately reflected in the regulations. Although *Statutory Instruments No. 500* 2, a subsequent revision of No. 257, acknowledges some of these concerns, considerable ambiguity remains around the key issue of when, or indeed if, commissioners will be required to tender all services.

The BMA has long argued that mandatory competition for all services risks fragmentation of services, creates unnecessary transaction costs, and increases scope for legal challenge, making it harder for the NHS to deliver high-quality, cost-effective and integrated care to patients.

At a meeting in March 2013, the BMA’s General Practitioners Committee (GPC) discussed the regulations and reached the view that the rewritten regulations did not satisfactorily assuage GPs’ concerns and there was a lack of clarity for commissioners about the circumstances in which competition does not have to be used. The GPC therefore called for the withdrawal of the regulations.

Concerns about the regulations are shared by many organisations across the health sector, and the House of Lords Secondary Legislation Committee raised in two reports that the statutory instruments required additional parliamentary scrutiny. 3,4 Its latest report drew attention to the lack of clarity stating that:

‘This wide range of interpretations of the substitute regulations is, we believe, likely to translate into uncertainty about how they will operate and will, in turn, result in commissioners conducting unnecessary tendering processes simply to ensure that their decision will be “safe” under the law.’ 5
Background

Monitor’s powers under the Health and Social Care Act 2012

To fully understand the implementation of the regulations, it is necessary to look at the wider context of the Act. Monitor will have the same powers currently exercised by the Office of Fair Trading in relation to anti-competitive behaviour. Under the Act, Monitor has, as its main duty, to ‘protect and promote the interests of people who use health care services by promoting provision of health care services which (a) is economic, efficient and effective and (b) maintains or improves the quality of the services.’

Section 62(3) says:

‘Monitor must exercise its functions with a view to preventing anti-competitive behaviour in the provision of health care services for the purpose of the NHS which is against the interests of people who use such services.’

Section 62(4) says:

‘Monitor must exercise its functions with a view to enabling health care services provided for the purposes of the NHS to be provided in an integrated way…’

As a statutory body, Monitor must carry out its functions in accordance with the powers and duties conferred on it in primary legislation. In addition, the Secretary of State has power to make regulations which can impose further requirements on bodies carrying out functions under the Act (in accordance with the primary legislation).

Sections 75-77 of the Act gives the Secretary of State power to make regulations in relation to procurement, patient choice and competition. These sections confer the power to make regulations concerning Monitor’s ability to investigate and tackle anti-competitive behaviour by NHS England (previously known as the NHS Commissioning Board) and Clinical Commissioning Groups (CCGs), with the authority to direct commissioners to address breaches of the rules.

The Act sets the broad requirements around competition and anti-competitive behaviour for commissioners. Regulations cannot go further than the primary legislation under which they are made – to do so would be ultra vires and challengeable through the courts. Regulations are intended to provide greater clarity on what will be expected of commissioners and more detail on how
Monitor will operate in practice. If no regulations are made, Monitor would carry out its functions in accordance with primary legislation but with no further restrictions on its powers.

Monitor’s forthcoming guidance for commissioners on procurement and competition will add further vital detail on what will be expected of commissioners and how Monitor will discharge its functions in this area.

**Commissioners’ responsibilities under the Act**

The Act gives CCGs responsibility for arranging the commissioning and provision of services. The purpose behind the legislation was to put commissioning in the hands of clinicians.

The principal duties of CCGs are defined in Section 13 of the Act, in particular 13(4) which refers back to the duty to promote a comprehensive health service; CCGs would have to act consistently with that. We believe that there is nothing in the Act that would prevent regulations specifically saying that it is for CCGs to decide how best to procure services on behalf of the population they serve.

**Government assurances**

Throughout the passage of the Act and subsequent introduction of regulations, Ministers gave a number of assurances that commissioners would be free to commission services in the way they consider best and that there will be no compulsory competitive tendering placed on them:

> ‘….it is not the Government’s intention under clause 67 [Section 75] for regulations to impose compulsory competitive tendering requirements on commissioners, or for Monitor to have powers to impose such requirements.’
> **Rt Hon Simon Burns MP, Health and Social Care (Re-committed) Bill Committee, 12 July 2011**

> ‘I know many of you have read that you will be forced to fragment services, or put them to tender. This is absolutely not the case. It is a fundamental principle of the Bill that you as commissioners, not the Secretary of State and not regulators – should decide when and how competition should be used to serve your patients interests…’
> **Rt Hon Andrew Lansley MP letter to CCGs, 12 February 2012**
‘Clinicians will be free to commission services in the way they consider best. We intend to make it clear that commissioners will have a full range of options and that they will be under no legal obligation to create new markets, particularly where competition would not be effective in driving high standards and value for patients. As I have already explained, this will be made absolutely clear through secondary legislation and supporting guidance as a result of the Bill.’

Rt Hon Earl Howe, Health and Social Care Bill, 5th Day Report Stage, 6 March 2012

Consultation on the draft regulations

Following passage of the Act, a consultation on the draft regulations was published in July 2012. This detailed provisions for NHS England and CCGs under Sections 75-77 of the Act, on procurement, patient choice, anti-competitive behaviour and managing conflicts of interest.

The BMA’s response reiterated our firm belief that in the context of clinical commissioning under the Act, local commissioners are best placed to take the lead in deciding where and how to extend patient choice and that regulations must not act as a barrier to this.

The BMA also signed a submission from the staff side of the Staff Passport Group (a sub-group of the Social Partnership Forum), along with UNISON, the Royal College of Nursing, Managers in Partnership, the Chartered Society of Physiotherapy and Unite. This submission set out the unions’ joint opposition to the Act and its direction of travel as well as specific points on the regulations.

In developing the regulations, the Department of Health (DH) undertook a programme of engagement to inform stakeholders about the draft regulations and to gather views. There was engagement with the NHS trade unions during the consultative period through DH attendance at the Staff Passport Group and a special workshop on the regulations.

A number of the key concerns we raised to tighten up the draft regulations were taken on board by the DH in response to the consultation. These included strengthening requirements around conflicts of interest and amending a proposed ‘indispensability’ test in order to give commissioners more flexibility to restrict competition where they can show it is necessary to achieve benefits for patients.
Initial regulations – *Statutory Instruments No. 257*

On 13 February 2013, the Government laid the NHS (Procurement, Patient Choice and Competition) Regulations 2013 before Parliament. However, the wording of the regulations created confusion and concern over the impact of the competition elements of the Act in practice.

The main area of concern was around tendering and the circumstances in which commissioners would be able to award a contract without using competition. The regulations were unclear as to when commissioners would be able to legitimately restrict competition, stating that this would only be allowed for reasons of extreme urgency or for ‘technical reasons’. Concerns were raised about this being at odds with previous Government assurances that commissioners should be free to decide when and if it is appropriate to use competition to improve services. We believe that without further explanation of the circumstances, included in the scope of these ‘technical reasons’, the impact of the regulations on the ability of commissioners to decide whether it is appropriate to use competition is unclear and potentially damaging to the comprehensiveness and integration of services.

It was also not clear from the regulations alone whether commissioners would be able to prioritise integration over competition and choice without leaving themselves open to challenge from Monitor.

Earl Howe’s letter to Peers on 28 February 2013 stated that ‘commissioners would not be obliged to advertise or competitively tender where no market exists and there is only one provider capable of delivering their requirements.’

He gave examples of where this would be the case, including where the commissioner needs acute hospitals services accessible on single sites and where clinical volumes need to be maintained for patient safety. He also stated that ‘commissioners would not be obliged to fragment services to enable providers to compete or stimulate market entry where this would not be in patients’ best interests.’

Despite these assurances many, including the BMA, continued to raise concerns about the regulations not sufficiently matching previous assurances that commissioners would not be forced to engage in inappropriate competitive tendering. These assurances should be written into the regulations.
Revised regulations – Statutory Instruments No. 500

The Government announced that it would review and republish the regulations to clarify that rules around anti-competitive behaviour would go no further than the existing rules on competitive tendering and admitted that the wording of the regulations had ‘inadvertently created confusion and generated significant concerns about their effect.’ The BMA noted the Government’s efforts to address the confusion in the redrafted regulations and stressed that there needed to be much greater clarity for commissioners, and that CCGs should be free to place contracts with the most suitable providers in the best interests of patients.

The second set of regulations were laid in Parliament on 11 March 2013. Changes were made to Regulation 2 to add integration as a factor when considering procuring health care services (reflecting the provisions in the primary legislation). Regulation 5(2) in the original regulations was removed, leaving Regulation 5(1) as the only means of awarding a new contract without competition. Under this set of regulations, the test is whether a commissioner is satisfied that the services are capable of being provided only by that provider. Monitor is to issue guidance as to how this will be interpreted. Regulation 10(3) was also removed. The addition of regulation 15(2) means Monitor will not be able to direct a commissioner to hold a competitive tender. Additional provisions around integration have been included in the revised regulations.

However, Regulation 5 continues to be a key area of contention.

The BMA acknowledged that the Government had listened to concerns over the regulations and that the redrafted regulations, if combined with clear guidance, would help provide greater clarity. We stated that it is vital that competition does not hamper clinical autonomy and prevent innovation and integration, or undermine cooperation between commissioners and providers. As major NHS changes came into force on 1 April 2013, further guidance has still not been published and nor have assurances been given any greater force. This has created great uncertainty and anxiety for clinicians and patients, and left commissioners in a potentially vulnerable state. Despite assurances from the Government, we believe only explicit wording in the regulations themselves would allow patients, doctors and commissioners to understand unambiguously that ‘clinicians will be free to commission services in the way they consider best.’
Operation in practice – joint position of Monitor and NHS England

Monitor and NHS England have made it clear that in their view, it is for commissioners to decide if and when to introduce choice and competition where it is in the interests of patients, beyond the rights set out in the NHS Constitution.\(^9\)

In an interview with the Health Service Journal, the chief executive of Monitor stated that ‘we would be mad to enforce those rules in a way that leaves commissioners spending all their time running competitive processes because they’re terrified they’re going to get in trouble if they don’t.’\(^10\)

Despite these assurances, there is still confusion about how the regulations will operate in practice – the lack of clarity is illustrated by the following examples:

Example 1

It is important that commissioners are free to ‘bundle’ services where it is necessary to ensure quality and safety. Trauma and orthopaedic services are a good example of linked services that may be best supplied by one provider in some circumstances.

Trauma services, which provide emergency surgical treatment for patients with serious injuries, rely on staff and facilities from orthopaedic services to function effectively. Having orthopaedic services alongside trauma services ensures an adequate supply of experienced anaesthetists, surgeons, nurses and other healthcare professionals to deliver trauma surgery safely and to a high standard. Working in orthopaedics allows teams of healthcare professionals to gain a breadth of experience and skill that ensures they can also provide safe and high quality trauma services.

If commissioners were not allowed to bundle these services where they considered it to be in patients’ interests, there could be a serious impact on quality and safety. If routine orthopaedics were separated from trauma services, it is likely that there would not be enough healthcare professionals to deliver the trauma services effectively and those who were available would not have gained the same level of experience and skill necessary to provide a safe service. It is essential that commissioners are able to maintain or create bundled arrangements such as these where it is clearly in the interests of quality and safety that certain services are linked and supplied by the same provider.
Example 2

Commissioners use bundling for a variety of reasons, for example to ensure the overall viability of an essential local provider or to provide integrated care pathways.

Will the regulations allow commissioners to maintain or create new bundling arrangements with local providers, where this is in the best interests of patients and the local community, without running the risk of challenge? Or will commissioners be forced to unbundle all their contracts and run competitive tenders instead? Will commissioners be able to use bundling to fulfil their duties to enable services to be provided in a more integrated way, as per Regulation 2, or will Regulation 5 take precedence? It is vital that the regulations provide clarity on this.

What we are seeking

Given the direction of travel and specific duties established by the Health and Social Care Act 2012, it is vital that commissioners have as much detail as possible around what will be expected of them and how Monitor will perform its functions. In the future, Monitor may change its mind on the interpretation of its duty, and Ministerial assurances could be overridden. It is important for these assurances to be credibly written into the regulations.

The BMA is therefore calling for withdrawal of the second set of regulations, and is seeking their replacement with new regulations unambiguously reflecting the many Government assurances that commissioners will not be forced to use competition. This principle should be stated explicitly in the regulations.

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References

6. Health and Social Care Act 2012 S62(1)
11. Health Service Journal, ‘Monitor chief executive says it would be “mad” to force unnecessary tendering’, 3 April 2013