

EXPLANATORY MEMORANDUM TO
THE NATIONAL HEALTH SERVICE (PROCUREMENT, PATIENT
CHOICE AND COMPETITION) (No.2) REGULATIONS 2013

2013 No. 500

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.
2. **Purpose of the instrument**
 - 2.1 These Regulations impose requirements on the NHS Commissioning Board and clinical commissioning groups to ensure good practice when procuring health care services for the purposes of the NHS, to protect patients' rights to make choices and to prevent anti-competitive behaviour. The Regulations provide scope for complaints to, and enforcement by Monitor, an independent health regulator, as an alternative to challenging decisions in the courts.
3. **Matters of special interest to the Joint Committee on Statutory Instruments**
 - 3.1 None.
4. **Legislative Context**
 - 4.1 The Regulations are made under section 75 of the Health and Social Care Act 2012 (the 2012 Act). They set certain requirements on commissioners of NHS health care services to be enforced by Monitor.
 - 4.2 During the passage of the 2012 Act the Government responded to concerns about the future application of choice and competition in the health service by committing to retain the existing non-statutory administrative rules (The Principles and Rules for Cooperation and Competition), that concern procuring for clinical services, and place them on a firmer, statutory footing (see the Government response to the NHS Future Forum report, CM 8113)¹.
 - 4.3 The Regulations, therefore, are being used as the vehicle to deliver the Government's commitment and continue sector specific rules, building on the Principles and Rules for Cooperation and Competition, in the new health system.
 - 4.4 These Regulations will apply alongside the Public Contracts Regulations 2006 and do not affect their application.

¹ 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>)

4.5 These Regulations will revoke and replace the National Health Service (Procurement, Patient Choice and Competition) Regulations 2013.

5. Territorial Extent and Application

5.1 This instrument applies to England.

6. European Convention on Human Rights

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

- **What is being done and why**

7.1 The 2012 Act makes changes to how NHS health care is commissioned in England. The 2012 Act establishes a new NHS Commissioning Board and clinical commissioning groups who will commission the majority of NHS health care in England and between them will be responsible for over £80 billion of annual public expenditure.

7.2 The Regulations build on the existing administrative rules, The Principles and Rules for Cooperation and Competition, first established by the Government in 2007 to protect patients' interests, and reviewed in 2010 to ensure they remain consistent with the White Paper: Equity and Excellence: Liberating the NHS². The Regulations are necessary, however, because the administrative rules will not apply to the commissioners established under the 2012 Act who have greater autonomy within that legislative framework. The Secretary of State will no longer have extensive general powers to intervene in the NHS; these are replaced with specific and limited powers. The Regulations, therefore, provide for important safeguards to protect patients' interests.

7.3 Part 2 of the Regulations places requirements on these new bodies to improve the quality and efficiency of services, including through services being provided in an integrated way, by procuring from the providers most capable of meeting that objective and delivering best value for money. In doing so commissioners are required to always act transparently, proportionately, without discrimination and consider where more integration, patient choice and competition would be appropriate means to achieving their aims. The overarching intention is to ensure that patients have access to the highest quality services and that best value is achieved for the taxpayer. The Regulations are intended to cover all actions and decisions taken by commissioners in relation to the procurement of healthcare services.

² The revised Principles and Rules for Cooperation and Competition, published by the Department of Health on 30 July 2010. The document can be accessed at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_118221

7.4 The Regulations place further requirements on commissioners to ensure accountability and transparency in their expenditure. In particular:

- to record the rationale for their decisions and how they have met their duties as to quality, effectiveness and the promotion of integration;
- to publish details of the contracts that they have awarded;
- to not award contracts where conflicts or potential conflicts of interest have, or appear, to affect the integrity of the decision; and
- not to engage in anti-competitive behaviour unless to do so is in the interest of patients. Regulation 10 makes clear that behaviour in the interests of patients may include services being provided in an integrated way or co-operation between providers in order to improve the quality of services. This reflects the Government's firm view that competition is a means to improving services and not an end in itself.

7.5 Regulation 5 provides for commissioners to award a new contract without a competition where there is only one capable provider. There has been no change in policy from the requirements of the Principles and Rules for Cooperation and Competition and the supporting procurement guidance. Monitor's guidance on the regulations will make this clear.

7.6 The 2012 Act has established Monitor as an independent regulator for the health care sector with a duty to protect and promote the interests of people who use health care services. Part 3 of the Regulations provide for Monitor to investigate potential breaches of the requirements and to take action to ensure that patients' interests are protected. It provides for complaints to Monitor, a regulator with specific knowledge of the health sector, as an alternative to bringing actions through the courts for breaches of the Public Contract Regulations 2006 (in so far as they apply to health care services).

7.7 Part 2 of the Regulations also place a requirement on the NHS Commissioning Board not to restrict patients' rights of choice of GP practice, or the choice of practitioner within the practice. The Regulations also provide for Monitor to protect those rights and the other rights to choice that patients have under the NHS Constitution, including the right to exercise choice at referral to secondary elective care services as required under Part 8 of the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012. There is evidence that these rights have been frustrated in the past³ and therefore Monitor will seek to ensure that they continue to be protected.

³ "Review of the Operation of 'Any Willing Provider' for the provision of routine elective care" was published by the Cooperation and Competition Panel on 28 July 2011. The Report can be accessed at: http://www.ccpanel.org.uk/content/cases/Operation_of_any_willing_provider_for_the_provision_of_routine_elective_care_under_free_choice/280711_AWP_Review_Final_Report.pdf

7.8 The Regulations provide for Monitor to direct a commissioner to prevent or mitigate a failure to comply with the requirements, or remedy a failure to comply. Alternatively, Monitor has the power to accept an undertaking from a commissioner in lieu of a direction. The Regulations provide for Monitor to set aside a contract that a commissioner has entered into where there has been a sufficiently serious breach of the Regulations.

7.9 The Regulations do not give Monitor the power to direct where or when commissioners should introduce competition or patient choice of provider. In particular, the regulations provide that Monitor may not direct a commissioner to hold a competitive tender for a contract for the provision of health care services. Monitor's role is to investigate whether commissioners have respected due process, considered the full range of options and followed the requirements in the Regulations when procuring health care services.

8. Consultation outcome

8.1 Proposals setting out draft requirements were the subject of a formal consultation exercise which ran from 15 August to 26 October 2012. The Department worked closely with the NHS Commissioning Board and Monitor in developing the proposals. In addition to consulting with individuals working in the commissioning and provision of NHS services, over 80 responses to the consultation were received. Responses were received from a wide range of organisations including commissioners, providers, trade unions, professional and representative organisations.

8.2 Overall, stakeholders responded favourably with broad support for the approach being proposed, in particular:

- there was broad support for the proposed approach to use the regulations to set principles of good procurement rather than more prescriptive rules in order to retain flexibility for commissioners;
- almost all respondents agreed that the rights of patients to make choices as enshrined in the NHS Constitution should be protected;
- there was also broad support for the approach proposed whereby restrictions on competition would be balanced against patient benefits.

8.3 Of concern to many respondents was that there should be sufficient support and guidance published for commissioners to accompany the Regulations.

8.4 A full analysis of the responses to the consultation is available from the Department's website: www.dh.gov.uk

9. Guidance

9.1 Section 78 of the 2012 Act places a duty on Monitor to publish guidance for commissioners on compliance with the Regulations and how it intends to exercise its enforcement powers. Monitor must consult and must obtain the approval of the Secretary of State before the guidance is published.

The NHS Commissioning Board will also publish guidance in early 2013 to help clinical commissioning groups understand and work within the Regulations, including in relation to conflicts of interest. The NHS Commissioning 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.

10. Impact

10.1 The direct impact on business, charities or voluntary bodies is negligible.

10.2 The direct costs on the public sector is negligible. There could be indirect costs associated with commissioners' compliance with statutory regulations instead of non-statutory rules. This is difficult to estimate and could be negligible given the regulations are consistent with EU and UK procurement law with which commissioners are already required to comply.

10.3 An Impact Assessment is available from the Department of Health's website: <http://transparency.dh.gov.uk/category/transparency/ias/>

11. Regulating small business

11.1 The legislation does not apply to small businesses.

12. Monitoring & review

12.1 Monitor will monitor commissioners' compliance with the Regulations as part of its responsibilities under the Regulations. The Department of Health will keep Monitor's performance under review through quarterly financial and accountability stocktakes. The operation of the Regulations will be kept under review and updated as required. In addition, the Department of Health will be commissioning an independent evaluation programme of the impact of its policies on the NHS.

13. Contact

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