

EXPLANATORY MEMORANDUM TO
THE NATIONAL HEALTH SERVICE COMMISSIONING BOARD AND CLINICAL
COMMISSIONING GROUPS (RESPONSIBILITIES AND STANDING RULES)
(AMENDMENT) REGULATIONS 2017

2017 No. 296

1. Introduction

- 1.1 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 amend The National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 (“the principal Regulations”), which provide for a range of matters relating to the functions and commissioning responsibilities of the National Health Service Commissioning Board (“the Board”) and clinical commissioning groups (“CCGs”). The amendment amends the list of prescribed health services which the Board must commission for people with rare and very rare conditions

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

- 3.1 None.

Other matters of interest to the House of Commons

- 3.2 As this instrument is subject to the negative procedure and has not been prayed against, consideration as to whether there are other matters of interest to the House of Commons does not arise at this stage.

4. Legislative Context

Specialised Services

- 4.1 Section 3B of the National Health Service Act 2006 (“the 2006 Act”) enables the Secretary of State to make regulations requiring the Board to arrange, to such extent as it considers necessary to meet all reasonable requirements, for the provision of certain services. In particular, under section 3B(1)(d) and (2), regulations may prescribe certain services or facilities for commissioning by the Board, subject to the Secretary of State considering it is appropriate for the Board to have commissioning responsibility (rather than CCGs), and having regard to certain specified factors set out in section 3B(3) (as to which factors, see paragraph 7.4).
- 4.2 Schedule 4 to the principal Regulations lists those health services for persons with rare and very rare conditions which the Board must commission pursuant to regulations 7, 10 and 11 of those Regulations. These Regulations revise and update Schedule 4, in particular by inserting one new specialist service- uterine transplantation services.

4.3 Prior to making regulations under section 3B of the 2006 Act, the Secretary of State must obtain appropriate advice and must consult the Board, as required under subsection (4) of that section. The Secretary of State has obtained advice as to the desirability of the Board having statutory commissioning responsibilities as provided for in these Regulations and has consulted with the Board about the amendments to prescribed services. In light of that consultation and advice, and, having regard to the factors prescribed in section 3B(3) of the 2006 Act (summarised below at paragraph 7.4), the Secretary of State has decided to make these amending Regulations.

5. Extent and Territorial Application

5.1 This instrument extends to England only.

5.2 This instrument applies to England only.

6. European Convention on Human Rights

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

7. Policy background

Specialised services

7.1 CCGs are responsible for commissioning the majority of NHS services. The NHS has always sought to give the responsibility for planning and commissioning services to local health bodies where appropriate. This allows decisions about local services to be made as close to patients as possible, by those who are best placed to work with patients and the public to understand their needs. This enables services to be organised and integrated around the needs of local populations and supports the autonomy of CCGs.

7.2 Although most services in the NHS, other than primary care, are commissioned by CCGs, there are different arrangements for commissioning certain services, including those for people with rare and very rare conditions where the services are often high cost and where expertise needs to be concentrated. In these cases, the Board has been given commissioning responsibility. The obligation on the Board set out in the principal Regulations is, in terms, that it must arrange to such extent as it considers necessary to meet all reasonable requirements for the provision of the specified services as part of the health service. In keeping with statutory duties on the Secretary of State under the 2006 Act, these arrangements are intended to ensure consistent, high quality care and consistent access to NHS services required by those small groups of patients with rare and very rare conditions, on the basis that national commissioning will achieve more focussed provision, using selected providers and enabling access to experts, thereby affording highly specialist care to the relatively small numbers requiring it. The amendments concerning specialised services also uphold the NHS Constitution principle that “everyone counts”.

7.3 A group of clinical experts and lay persons, known as the Prescribed Specialised Services Advisory Group (PSSAG), was established by the Secretary of State to provide advice to Ministers on which services for persons with rare and very rare conditions are specialised and should be commissioned nationally by the Board. On 8th December 2016, and after having received advice from PSSAG, the Secretary of State for Health commenced formal consultation with the Board on the changes

PSSAG had recommended to the portfolio of services contained within Schedule 4 to the principal Regulations. The recommended change is:

- To add a new service: uterine transplantation services.

7.4 The Secretary of State, having obtained PSSAG's advice, considers these changes appropriate, having regard to the four factors set out in section 3B of the 2006 Act. These are:

- The number of individuals requiring the provision of the service or facility;
- The cost of providing the service or facility;
- The number of persons able to provide the service or facility; and
- The financial implications for CCGs if they were required to arrange for the provision of the service or facility.

7.5 NHS England does not currently commission uterine transplantation services and this proposal was for a national commissioned specialised service for this treatment. PSSAG recommended, and ministers agreed, uterine transplantation met these four criteria. PSSAG discussed the service with regard to the four statutory factors and agreed that the number of people requiring the service was low, whilst the cost of providing the service was high. The number of people able to provide the service was low as there is just one team currently undertaking research in this area in the UK. PSSAG anticipated that the impact on CCGs, if they were required to commission this service, could be significant.

PSSAG agreed that if this service should be commissioned by the NHS, then NHS England should be the responsible commissioner. PSSAG agreed to recommend to Ministers that this service did meet the requirements for national commissioning with regard to the four statutory factors

8. Consultation outcome

8.1 Specialised services: In accordance with the Secretary of State's powers under section 3B of the 2006 Act, the Secretary of State has sought appropriate advice as described above from the PSSAG, which is an independent stakeholder advisory group, established by the Department to advise Ministers on specialised services for persons with rare and very rare conditions. PSSAG includes clinical experts and lay members representing patient interests, and representatives of CCGs. Further, before deciding whether to make these Regulations, the Secretary of State has also consulted the Board and has taken into account its comments and advice. The Board is supportive of the amendment made by these Regulations in respect of its commissioning functions and have agreed to take responsibility for commissioning uterine transplantation services from April 2017.

9. Guidance

9.1 Specialised services: the Board publishes a number of documents explaining commissioning arrangements in this area, which include its "Manual of Prescribed Specialised Services", which sets out in detail the specialised services it commissions pursuant to the principal Regulations. This is available from its website <http://www.england.nhs.uk/commissioning/spec-services/key-docs/> or by post by telephoning 0300 311 22 33 (Monday to Friday 8am to 6pm, excluding English Bank Holidays) or writing to the Board at PO Box 16738, Redditch, B97 9PT. The Board

will notify CCGs, as well as any relevant providers of services, of the new commissioning arrangements.

10. Impact

- 10.1 There is no impact on business, charities or voluntary bodies.
- 10.2 There is no impact on the public sector.
- 10.3 An Impact Assessment has not been prepared for this instrument.

11. Regulating small business

- 11.1 The legislation does not apply to activities that are undertaken by small businesses.

12. Monitoring & review

- 12.1 The Secretary of State remains accountable for keeping the Board's effectiveness under review and annually assessing its performance in line with his duties under the National Health Service Act 2006.
- 12.2 The principal Regulations (which these Regulations amend) will be reviewed annually and updated as required.

13. Contact

- 13.1 In relation to amendments concerning specialist services, contact Tilly King at the Department of Health, tel: 02072 106 217 or email: Tilly.King @dh.gsi.gov.uk, who can answer any queries regarding those aspects of the instrument.