EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (FUNCTIONS OF STRATEGIC HEALTH AUTHORITIES AND PRIMARY CARE TRUSTS AND ADMINISTRATION ARRANGEMENTS) (ENGLAND) (AMENDMENT) REGULATIONS 2012

2012 No. 417

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 (Functions of Strategic Health Authorities and Primary Care Trusts and Administration Arrangements) (England) Regulations 2002[1] ("the principal regulations") which set out the specialised services whose provision is to be secured in England by Strategic Health Authorities (SHAs), rather than Primary Care Trusts (PCTs). The Regulations add eight new services that will be nationally commissioned by SHAs from 1 April 2012. They also amend the descriptions of a number of existing services so as to reflect more accurately the descriptions used in the health service.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Legislative Context

4.1 The principal regulations provide for the functions of the Secretary of State relating to the health service to be exercisable in England by Strategic Health Authorities and Primary Care Trusts. These include functions under section 3(1) of the National Health Service Act 1977 for the provision of medical, nursing and certain other services. This section was later re-enacted as section 3(1) of the National Health Service Act 2006.

4.2 In general, the principal regulations do not enable SHAs to enter directly into agreements with providers (such as NHS Trusts and Foundation Trusts) for the provision of health care services. However, from April 2007, the principal regulations were amended, by the National Health Service (Functions of Strategic Health Authorities and Primary Care Trusts and Administration Arrangements) (England) (Amendment) Regulations 2007[2], to allow SHAs to commission specific highly specialised services in England, as set out in Schedule 5 to the principal Regulations.

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[1] SI 2002/2375
[2] SI 2007/559

4.3 These new regulations will update Schedule 5 to the principal regulations to include an additional eight services whose provision is to be secured by SHAs. They will also update references to 5 of the existing services to more accurately reflect the terms used in the health service.

5. Territorial Extent and Application

5.1 This instrument applies to England only.

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 Although most services in the NHS are commissioned by PCTs, there are different arrangements for commissioning specialised services at national level. The Advisory Group for National Specialised Services (AGNSS) advises Ministers on which services should be commissioned nationally.

7.2 On 7th February 2012, and after having received advice from AGNSS, the Secretary of State for Health and the Parliamentary Under-Secretary of State for Quality (Lords) decided that eight new services should be nationally commissioned as part of the portfolio of highly specialised services. These services are:

i. Adult ataxia telangiectasia service
ii. Alkaptonuria service
iii. Beckwith Wiedemann syndrome with macroglossia service
iv. Behçet's syndrome service
v. Breast radiotherapy injury rehabilitation service
vi. Ex-vivo partial nephrectomy service
vii. Primary ciliary dyskinesia management service
viii. Severe acute porphyria service

7.3 Further detail on these services can be found in the table at Annex A. These services are being in are being included within the national arrangement for commissioning specialised services, on the basis of the rarity of the condition, the small numbers of patients involved (often at high treatment costs) and the need to concentrate clinical expertise in a number of centres. In effect these arrangements operate as a national insurance mechanism for which all Primary Care Trusts pay through a clawback on their allocations. This funding is made available to London SHA to commission these services on a national basis on behalf of the other SHAs in England.

8. Consultation outcome

8.1 The recommendations were all agreed by AGNSS. The membership of AGNSS includes patient/public involvement representatives as well as NHS commissioners, policy makers and representatives of the Royal Colleges and professional bodies. No additional consultation has been undertaken on these proposed additions to the national specialised commissioning portfolio beyond the policy process.

9. Guidance

9.1 Once the new regulations have been made, copies will be shared with the National Specialised Commissioning Team (the team that supports AGNSS). An update will also appear in the NHS Chief Executive's bulletin 'The Week' before the end of March 2011, detailing the commissioning arrangements for the new services specified in the schedule.

10. Impact

10.1 The impact on business, charities or voluntary bodies is none.

10.2 The impact on the public sector is specific only to:

- SHAs, and in particular the SHA known as NHS London, which exercises the SHAs functions and commissions highly specialised services; and
- Providers of highly specialised services at NHS Trusts and NHS Foundation Trusts who contract with NHS London.

10.3 An impact assessment has not been prepared for this instrument.

11. Regulating small business

11.1 The legislation does not apply to small business.

12. Monitoring & review

12.1 The Department of Health remains accountable for policy changes through Ministers and holds NHS London accountable for operational issues through a Memorandum of Understanding. SHAs are responsible for commissioning specialised services, but have delegated authority to NHS London for the commissioning of services at a national level.

12.2 Subject to the passage of the Health and Social Care Bill it is intended that from 1 April 2013 the new NHS Commissioning Board will have direct responsibility for commissioning those services currently described as specialised services, provided they meet the 4 factors set out on the face of the Bill. These are:

- the number of individuals who require 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 Clinical Commissioning Groups if they were required to arrange for the provision of the service or facility.

12.3 This will include the specialised services commissioned nationally by the National Specialised Commissioning Team within London SHA and regionally by Specialised Commissioning Groups. Commissioning these services directly, through one national commissioner to a national standard should ensure better planning and co-ordination of services which will be of benefit to patients. It is expected that the new arrangements will come into effect from 1 April 2013.

12.4 This is therefore expected to be the final year that the arrangements for handling additions to the national portfolio are handled in this way.

13. Contact

Sarah Bramley-Harker at the Department of Health, Tel: 0113 2546708 or email: sarah.bramley-harker@dh.gsi.gov.uk can answer any queries regarding the instrument.

Service	Description
Adult ataxia telangiectasia service	This condition starts in early childhood and affects the nervous and immune systems resulting in severe disability and premature death. This service will provide support to children in the transition from children's to adults service. There are expected to be 60-70 patients in England.
Alkaptonuria (AKU) service	This is a condition that causes considerable ill health, particularly in people over the age of 30, through premature destruction of the joints and spine. This service will help to ensure more coordinated care. There are estimated to be 50-70 patients with the condition in England. .
Beckwith Wiedemann syndrome (BWS) with macroglossia service	This condition causes facial disfigurement leading to problems with feeding, speech and teeth. This service will provide expert care for these patients. There are estimated to be between 15-18 patients per annum.
Behçet's syndrome service	This disorder affects the body's immune system and causes blindness, mouth and genital ulcers. This service aims to provide better coordination of care and quicker diagnosis. There are estimated to be 450-490 patients in England.
Breast radiotherapy injury rehabilitation (RAGE)	This service provides rehabilitation to women who sustained injuries from exposure to high levels of radiation as part of their breast cancer care in the 1970s and 80s. There are estimated to be 250 patients in England but this will reduce over time.
Ex-vivo partial nephrectomy (EPN) service	This is a specialised operation for kidney cancer. The kidney is removed, the cancer cut out and then the kidney is reimplanted back into the patient. This

	avoids dialysis for the small number of patients with only one kidney. There are expected to be between 10-20 patients per annum.
Primary ciliary dyskinesia (PCD) management service	This is an inherited rare condition affecting the lungs and ear, nose and throat. This service will provide better management of the care that patients receive including a more structured transition to adult care. There is expected to be an active caseload of around 300 cases.
Severe acute porphyria service	This is a severe, inherited, condition caused by enzyme deficiency. It affects the nervous system of young adults and can result in permanent disability or even death. This service will provide better coordination of care and more consistent prescribing of the drug haem arginate. There are estimated to be between 126 and 200 patients in England with severe porphyria.