EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE COMMISSIONING BOARD AND CLINICAL COMMISSIONING GROUPS (RESPONSIBILITIES AND STANDING RULES) (AMENDMENT) REGULATIONS 2015

2015 No. 415

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 functioning and commissioning responsibilities of the National Health Service Commissioning Board ("the Board") and clinical commissioning groups ("CCGs"). The amendments –

- make amendments to the list of prescribed health services which the Board must commission for people with rare and very rare conditions;
- make saving and transitional provision in respect of one of the amendments relating to specialised services; and
- specify the rates payable by CCGs/the Board where NHS-funded nursing care is provided in residential accommodation arranged by a local authority in Northern Ireland or Scotland..

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

3.1 None.

4. Legislative Context

Specialised Services (regulation 2)

4.1 Section 3B of the National Health Service Act 2006 ("the 2006 Act") enables regulations to be made by the Secretary of State requiring the Board to arrange for the provision of certain services. Part 3 of and Schedules 2, 3 and 4 to the principal Regulations 2012 specify those services. These are services in addition to those that the Board will be responsible for commissioning under section 4 (high security psychiatric services) and Parts 4 to 7 (primary care) of the 2006 Act. 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 two new specialist services and expressly removing wheelchair services from within paragraph 135. A more detailed explanation is annexed to this Memorandum.

4.3 Transitional and saving provision is made in a new regulation 11A to be inserted into the principal Regulations in respect of the change affecting wheelchair services as a specialised service. They provide for the Board to continue to have statutory commissioning responsibility after the date the amendments to Schedule 4 come into force (1 April 2015) so long as a commissioning contract for affected services existing immediately before that date remains in place as between the Board and the provider, and only in respect of services to the extent they are provided under such a contract or such contracts. When, on or after 1 April 2015, the Board and individual CCGs agree with providers to novate an affected commissioning contract to a CCG, or the Board and a provider agree to terminate their contract on or after that date, or where the contract otherwise terminates, that duty ends so far as the affected services provided under the particular contract(s) are concerned. Statutory commissioning responsibility to that extent then falls to the CCG pursuant to section 3 of the 2006 Act, with the Board retaining responsibility for commissioning such affected services only to the extent they are provided under *other* contracts which have not been novated or otherwise terminated. This saving and transitional provision avoids overlap between, on the one hand, CCGs' statutory commissioning duties under section 3 and powers under section 3A of the 2006 Act, and on the other, the Board's statutory commissioning duties pursuant to section 3B of that Act.

4.4 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 of its no longer having responsibility for specialised wheelchair services (more detail is set out under "Policy background") The Secretary of State has also 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) (summarised below), the Secretary of State has decided to make these amending Regulations.

NHS funded nursing care (regulation 3)

4.5 Section 6E of the 2006 Act was inserted by section 20 of the Health and Social Care 2012 Act ("the 2012 Act"). It enables the Secretary of State to impose requirements on NHS England and CCGs when they are exercising their functions of commissioning health services. The requirements are known as the "Standing Rules", because they are intended to set core, ongoing requirements for the health service. The first Standing Rules were made as part of the principal Regulations, and were amended in 2013 and 2014.

4.6 These regulations amend Part 6 of the principal Regulations to specify the rates for NHS-funded nursing care payable by the relevant body (the Board or a CCG) where it consents to the provision of nursing care in residential accommodation in Northern Ireland or Scotland arranged by a local authority in accordance with relevant provisions of the Care Act 2014. Local authorities are prohibited by section 22 of the Care Act 2014 from meeting needs under that Act by providing or arranging the provision of services or facilities that it is the responsibility of the NHS to provide. However, despite this prohibition, local authorities are permitted under sections 22(4) and 22(5) of the Care Act 2014, to arrange for the provision of accommodation together with the provision of nursing care, if they obtain consent to arrange for the provision of nursing care from the appropriate relevant body (or seek that consent subsequently, in urgent cases where temporary accommodation is arranged). Where a CCG is the relevant body, the Care and Support (Provision of Health Service) Regulations 2014 (SI 2014/2821) identify the CCG from whom consent must be obtained for these purposes in respect of the person concerned.

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

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 some 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 responsibility for commissioning them. 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 are specialised and should be commissioned nationally by the Board for persons with rare and very rare conditions. On 18 December 2014, and after having received advice from PSSAG, the Secretary of State for Health commenced formal consultation with the NHS Commissioning Board on the changes PSSAG had recommended to the portfolio of services contained within Schedule 4 to the principal Regulations. The recommended changes are:

i. To add a new service: Adult highly specialist oesophageal gastric services in the form of gastro-electrical stimulation for patients with intractable gastroparesis.
ii. To add a new service: Highly specialist adult urological surgery services for men.
iii. To expressly exclude wheelchair services from within Specialist services to support patients with complex physical disabilities (so that all wheelchair services would be commissioned by CCGs).
iv. To omit and substitute existing paragraphs to provide greater clarity on the services prescribed.

(Other recommendations made by PSSAG are not reflected in the current amendments.)

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:

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

Further detail on these services and the policy reasons for amendments can be found in the table at the Annex to this Memorandum.

7.5 The intention of the saving and transitional provision mentioned in paragraph 4.3 is to facilitate flexible transfer arrangements for the Board to pass on its commissioning responsibilities to CCGs.

NHS-funded Nursing Care

7.6 NHS-funded Nursing Care is the funding provided by the NHS to care homes providing nursing, to support the provision of nursing care by a registered nurse for those assessed as eligible. Where an individual has a need for care from a registered nurse and it is determined that the individual's overall needs would be most appropriately met in a care home providing nursing care, this leads to eligibility for NHS-funded Nursing Care. Once the need for such care is agreed, the relevant body's responsibility to pay a flat rate contribution to the care home towards registered nursing care costs arises.

7.7 Schedule 1 to the Care Act 2014 puts in place a legislative framework that supports cross-border residential care placements. In essence, it makes clear that if a local authority in England places a person into residential care in Scotland, Wales or Northern Ireland, then the local authority in England retains responsibility (including financial) for that individual. This supports the general principles of ordinary residence..

7.8 A local authority may decide to place a person cross-border in order for them to be closer to a support network of friends and/ or family; hence supporting that person's well-being. A local authority may arrange for the provision of nursing care for a person for whom it arranges accommodation, with the consent of the relevant body with commissioning responsibility for that person, in accordance with section 22(4) and, where applicable, sections 22(5) and 22(9) of the Care Act 2014.

7.9 If the relevant body assesses the person in question as eligible for NHS-funded nursing care then the NHS commissioning body in England from which the person will be placed will retain responsibility for funding this care, which will be delivered in practice by the NHS organisation responsible for the area into which the person has been placed.

7.10 The purpose of these provisions is to amend the NHS Standing Rules to specify the rates at which the English commissioning body must reimburse the service provider in another territory of the UK for the cost of this NHS funded nursing care. The rate specified for Northern Ireland reflects that applicable at 1 April 2014 in Northern Ireland, ie £100 per week. The rate specified for Scotland with effect from 1 April 2014 is £78 per week, taking account of the current rate of £77 per week, and the likely increase to £78 with effect from that date.. (Provision is not made in respect of Wales as a separate arrangement has been reached with the Welsh Assembly Government. In the case of an individual placed by an English local authority into a care home in Wales who is eligible for NHS nursing care, the NHS organisation in Wales will pay the NHS nursing care costs (the cost of the care accommodation will remain the responsibility of the English local authority).) We understand that the devolved authorities in Northern Ireland and Scotland intend to make arrangements in due course to ensure that in the case of individuals placed from Northern Ireland or Scotland into residential care accommodation in England, who are eligible for NHS nursing care, then the NHS body in

Northern Ireland or Scotland will remain responsible for paying these costs to the appropriate service provider in England".

Duty as to promoting autonomy of bodies carrying out functions under the 2006 Act

7.11 With regard to the Secretary of State's duty in relation to autonomy, the Secretary of State has taken advice from and consulted the Board before making the changes in relation to specialised services under section 3B. Where services are required to be commissioned by the Board in accordance with the amendments in these Regulations, it has autonomy to determine how these services are commissioned and delivered. Likewise, where CCGs are to assume commissioning responsibility, they have similar autonomy in fulfilling their duties to commission services to the extent necessary to meet reasonable requirements of those they have responsibility for.

7.12 In relation to the amendments concerning NHS funded nursing care, although these impose a duty on CCGs to make such payments at prescribed rates, this is outweighed by the overriding importance of providing a comprehensive service to patients: the policy avoids detrimental impacts on the funding of nursing care where a patient has family or other reasons for being placed with care services in Scotland or Northern Ireland. The autonomy of CCGs is supported by the fact that a local authority in England that wishes to place an individual cross-border must seek the consent of the CCG should NHS-funded nursing care be required.

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 Prescribed Specialised Services Advisory Group, which is an independent stakeholder advisory group, established by the Department to advise Ministers on specialised services for persons with rare and very 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 amendments which are made by these Regulations respect of its commissioning functions.

8.2 **NHS funded nursing care** – a public consultation exercise was carried out in relation to the Care Act 2014 cross-border provisions and can be found at https://www.gov.uk/government/consultations/updating-our-care-and-support-system-draft-regulations-and-guidance or by writing to: the Ministerial Correspondence and Public Enquiries Unit, Department of Health, Richmond House, 79 Whitehall, London SW1A 2NS. The intention to amend the NHS Standing Rules was made clear in the statutory guidance that accompanied the Care Act 2014. No comments on the commitment to change the Standing Rules were received.

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 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. Regards wheelchair services, the Board will work with CCGs to support them in assuming commissioning responsibilities for these services.

9.2 **NHS funded nursing care**: Statutory guidance on the Care Act 2014 is available at:
https://www.gov.uk/government/publications/care-act-2014-statutory-guidance-for-implementation or by writing to: the Ministerial Correspondence and Public Enquiries Unit, Department of Health, Richmond House, 79 Whitehall, London SW1A 2NS.
Paragraphs 21.46 to 21.50 relate to NHS-funded nursing care for cross-border residential care placements.

10. Impact

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

10.2 The impact on the public sector is specific only to commissioners and providers of specialised services at NHS Trusts and NHS Foundation Trusts. The impact on the Board as the commissioners of the additional specialist services is to increase marginally the range of services for which it has commissioning responsibility. The impact on CCGs in relation to wheelchair services is marginal. Budget adjustments as between the Board and CCGs as commissioners are anticipated to be made meaning that the overall financial impact of these amendments in terms of NHS commissioning is neutral

10.3 NHS funded nursing care - there is no additional burden placed on the public sector as a result of this instrument. The instrument does not result in more NHS funded nursing care – it simply allows it to be provided in a different territory of the UK.

10.4 An impact assessment has not been prepared for this instrument. In terms of commissioning generally, an Impact Assessment was prepared in relation to the Health and Social Care Bill 2012 which considered costs and costs savings of what is now the current commissioning model, at Annex A (pages 3-29) (to be found at www.dh.gov.uk/prod_consum_dh/group/dh_digitalassets/documents/digitalasset/dh_129917.pdf). A paper copy may be obtained by writing to: the

Ministerial Correspondence and Public Enquiries Unit, Department of Health, Richmond House, 79 Whitehall, London SW1A 2NS.

11. Regulating small business

11.1 The legislation does not apply to small business.

12. Monitoring & review

12.1 The Secretary of State remains accountable for keeping the NHS Commissioning 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 statutory guidance accompanying the Care Act 2014 advises local authorities that they may wish to consider processes for monitoring the use of cross-border placement.

12.3 The Regulations will be reviewed annually and updated as required.

13. Contact

In relation to amendments concerning specialist services, contact Sarah Samuel at the Department of Health, tel: 0113 2546708 or email: sarah.samuel@dh.gsi.gov.uk, who can answer any queries regarding those aspects of the instrument.

In relation to amendments NHS-funded nursing care, contact Niall Fry at the Department of Health, tel 020 7210 5260 or email: niall.fry@dh.gsi.gov.uk, who can answer any queries regarding those aspects of the instrument.

Annex

Amendments to Schedule 4	**Description**
After paragraph 3, insert – "3A. Adult highly specialist oesophageal gastric services in the form of gastro-electrical stimulation for patients with intractable gastroparesis."	Gastroparesis describes a condition where there is delayed emptying of gastric content without mechanical obstruction. Symptoms include nausea, vomiting, abdominal pain, distension and bloating. In severe cases these symptoms can result in failure to maintain body weight and hydration significant enough to require hospital admission. Gastro-electrical stimulation is a potential treatment option for individuals with intractable gastroparesis. The aim of gastroelectrical stimulation is reduced symptoms and enhanced gastric emptying. The four statutory factors have been considered: • The number of individuals requiring the provision of the service is small: the manufacturer of the device used for the process reported in 2010 that 80-100 individuals had had a device implanted. • The cost of providing the service: the cost of implanting the device is estimated at £16-£18k. • The number of persons able to provide the service or facility: implantation of the device requires specialist skills; the manufacturer reports there being six centres in England. • There is a moderate financial impact on CCGs if they were to commission this service.
Omit paragraph 11	On clinical advice, prescription for "Adult specialist intestinal failure services" omitted as it is regarded as encompassed within paragraph 102 "Severe intestinal failure service" and there is no need for commissioning arrangements to reflect a distinction.

For paragraph 31, substitute – "31. Bone conduction hearing implant services." Omit paragraph 76.	On clinical advice, the separate prescribed services for "Middle ear implantable hearing aid services" and "Bone anchored hearing aid services" have been replaced with a single prescription covering bone conduction hearing implants, which encompasses both the prescribed services it replaces.
For paragraph 59, substitute – "59. Highly specialist adult gynaecological surgery and urinary surgery services for women. 59A. Highly specialist adult urological surgery services for men."	To replace the current prescribed service (which exclusively covers services for women) with separate prescriptions for services for adult women and adult men. New service for adult men – applying the four statutory factors: • The number of individuals requiring the provision of the service is small. • The cost of providing the service is high. • The number of persons able to deliver the service is small because of the specialist surgical expertise required. • There would be a moderate financial implication for CCGs if they were to commission this service.
Omit paragraph 61 After paragraph 107, insert – "107A. Specialist colorectal surgery services"	On clinical advice, "Highly specialist colorectal surgery services" is omitted from the list of prescribed services and replaced with "Specialist colorectal surgery services" as the services intended to be prescribed are now more common than those that would normally be described as "highly" specialised.
For paragraph 116, substitute – "116. Specialist immunology services for adults with deficient immune systems. 116A. Specialist immunology services for children with deficient immune systems."	On clinical advice, specialist immunology services for adults and children should be treated as distinct services reflecting their different compositions. Accordingly, these Regulations separate the current prescription into distinct services for adults and children respectively.
At the end of paragraph 135, insert "excluding wheelchair services".	To remove specialist wheelchair services from "Specialist services to support patients with complex physical disabilities" so that they become the commissioning responsibility of CCGs.

	It has proved difficult to separately identify specialist wheelchairs and there are more providers of these wheelchairs than originally estimated, meaning that a distinction between specialist and other wheelchair services is no longer meaningful for commissioning purposes and specialist national commissioning is not now justified. Services for persons requiring specialist support for complex physical disabilities will continue to be commissioned by the Board, who will work with CCGs to ensure joined up service provision for patients.