

EXPLANATORY MEMORANDUM TO
THE NATIONAL HEALTH SERVICE COMMISSIONING BOARD AND CLINICAL
COMMISSIONING GROUPS (RESPONSIBILITIES AND STANDING RULES)
(AMENDMENT) REGULATIONS 2016

2016 No. 293

1. Introduction

1.1 This explanatory memorandum has been prepared by 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”). They –

- amend CCG responsibility for the provision of after-care services under section 117 of the Mental Health Act 1983 (“the 1983 Act”);
- make amendments to the list of prescribed health services which the Board must commission for people with rare and very rare conditions (and make related transitional provision); and
- amend certain requirements as to what terms must be included in a commissioning contract entered into by the Board or a CCG with a health service provider, so that the requirements closely reflect the regulatory duty of candour monitored and enforced by the Care Quality Commission.

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

After-care services under the 1983 Act (regulations 2 and 5)

4.1 When a patient has been detained under particular sections of the 1983 Act and then ceases to be detained, a duty is placed on the relevant CCG and local authority to provide, or arrange for the provision of, after-care services. After-care services is defined as services which have both the purpose of (i) meeting a need arising from or related to the person’s mental disorder and (ii) reducing the risk of deterioration of the person’s mental health condition (and, accordingly, reducing the risk of the person

requiring admission to hospital again for treatment for mental disorder) and are provided free of charge. Section 117(3) of the 1983 Act defines which CCG is responsible for providing after-care services. It provides that if, immediately before being detained, the person concerned was ordinarily resident in England, responsibility rests with the CCG in whose area the person was ordinarily resident. Similar provision is also made in respect of Wales. In any other cases, responsibility rests with the area where the person is resident or to which the person is sent to on discharge by the hospital in which the person was detained.

- 4.2 Regulation 14 of the principal Regulations specifies the circumstances in which the duty to provide after-care services can be placed on another CCG. Paragraph (2)(a) provides that this includes where a CCG has responsibility for a person by virtue of section 3(1A) of the National Health Service Act 2006. This means that when a CCG is, for example, responsible for commissioning a person's general medical services, responsibility for commissioning the person's after-care services would move to the same CCG. Regulation 2 of these Regulations omits Regulation 14(2)(a) of the principal regulations, which means that CCG responsibility will be determined in accordance with section 117(3) of the 1983 Act.
- 4.3 A transitional provision is included in regulation 5 which provides that where, immediately before these Regulations come into force, a CCG has responsibility for arranging the provision of after-care services under the principal Regulations, responsibility remains with that CCG for as long as that person needs after-care services or until that person is subsequently detained and entitled to after-care services again.

Specialised Services (regulation 4)

- 4.4 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, to such extent as it considers necessary to meet all reasonable requirements, for the provision of certain services. Part 3 of and Schedules 2, 3 and 4 to the principal Regulations specify those 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).
- 4.5 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, expressly removing specialist morbid obesity surgery services (in paragraph 118), and amending the name of ventricular assist devices services within paragraph 58. A more detailed explanation is annexed to this Memorandum.
- 4.6 Transitional and saving provision is made by means of the amendment to regulation 11A of the principal Regulations in respect of the change affecting specialist morbid obesity surgery as a specialised service. It provides for the Board to continue to have statutory commissioning responsibility after the date the amendments to Schedule 4 come into force (1 April 2016) 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 2016, 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.

- 4.7 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 specialist morbid obesity surgery services. 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) of the 2006 Act (summarised below), the Secretary of State has decided to make these amending Regulations.

Contractual Duty to be Open (regulation 3)

- 4.8 Regulation 16 of the principal Regulations places a requirement on the Board and CCGs, as commissioners, to include in contracts with providers of health services, requirements on providers to provide an apology and certain other information, in the event of certain incidents occurring in the course of patient care. However, the current regulation 16 enables commissioners to determine, via contracts, what the specifics of meeting the requirements would entail.
- 4.9 The amendments to regulation 16 require that the terms of the commissioning contracts are more prescriptive in that they must ensure that a health service provider complies with all the duties imposed on a registered person (whether or not the provider is such a registered person) by regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 ("the 2014 Regulations"). These duties include acting in an open and transparent way in relation to care and treatment provided, and relate to what must be done in the event of becoming aware that certain incidents have taken place in the context of the provision of care and treatment."

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

What is being done and why

After-care services under the 1983 Act

- 7.1 Regulation 14(2)(a) of the principal Regulations was adopted with the intent of streamlining responsibility for the provision of a person's general medical services with that for provision of that person's after-care services. In the light of experience of implementing the regulation, it has become clear that there is, in practice, an unintended consequence. In the event of the patient moving from one CCG area into another, responsibility for both general medical services and after-care services transfers to the new CCG.
- 7.2 CCGs and the Board have informed the Department of Health that the element of continuity of NHS commissioning responsibility for after-care services provided prior to 2012 is essential for the successful support of a particularly vulnerable group of patients. The Board and CCGs have advised that problems with identifying the responsible commissioner for after-care services are leading to long delays in discharge, to the detriment of the health and well-being of the patients in question. Where the patient moves from one CCG area to another, the after-care arrangements fall and must be reinstated in the new CCG. This can result in equally lengthy periods when the patient is not receiving any after-care services at all.
- 7.3 Thus, although regulation 14 of the principal Regulations achieved the original policy intent, the practical detrimental effect for patients significantly outweighs that objective. Omitting regulation 14(2)(a) will result in the rules under section 117(3) of the 1983 Act applying in all cases - i.e. commissioning responsibility will be identified by where a person was ordinarily resident immediately before being detained. Where ordinary residence cannot be established, the section 117(3) criterion of where a person was resident immediately before being detained would apply or (as a last resort) it would be where they are sent on discharge by the hospital where they were detained. This would be a return to the rules which applied prior to the date that the principal Regulations came into force. It would achieve the policy objective of ensuring continuity of care. The transitional provisions in regulation 5 of these Regulations will also achieve this in relation to patients who are already in receipt of after-care services.

Specialised services

- 7.4 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.
- 7.5 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”.

- 7.6 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 21 December 2015, 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:
- To add a new service: Mitochondrial donation
 - To add a new service: Specialist maternity care for patients diagnosed with abnormally invasive placenta.
 - To expressly exclude morbid obesity surgery for adults within specialist services.
 - To omit and substitute existing paragraphs to provide greater clarity on the services prescribed.
- 7.7 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.
- 7.8 Further detail on these services and the policy reasons for amendments can be found in the table at the Annex to this Memorandum.
- 7.9 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.

Contractual Duty to be Open

- 7.10 Regulation 16 of the principal Regulations (which came into force on 1st February 2013) introduced the contractual requirement on NHS providers, by means of requiring such terms to be included in commissioning contracts, to operate a duty of candour.
- 7.11 Following the publication of the report of the public inquiry into Mid-Staffordshire NHS Foundation Trust in February 2013, Sir Robert Francis recommended that a statutory duty of candour be introduced as part of the regulatory requirements for

registration by providers with the Care Quality Commission (“CQC”). This recommendation was taken forward alongside another recommendation from the inquiry that the requirements of regulation with CQC be simplified and focused.

- 7.12 The 2014 Regulations, also known as “the Fundamental Standards of Quality and Safety” were developed throughout 2013-2014, came into force in December 2014, and included the duty of candour in regulation 20. The duty of candour places a requirement on registered providers of health and adult social care, when carrying out activities which are prescribed as regulated activities under those Regulations, to be open with patients and service users about failings in care. The duty requires all providers registered with CQC to inform patients or their families if they believe treatment or care has caused death or serious harm, and provide an explanation and, where appropriate, an apology. CQC will decide when to take enforcement action for a failure to meet the duty of candour, including whether to bring a prosecution against a provider.
- 7.13 The introduction of the statutory duty of candour in the 2014 Regulations monitored and enforced by CQC, meant that there were two sets of regulations that impose similar requirements on providers. It makes sense to regularise this position and have only one duty of candour applying to providers across the sector. The duty of candour set out in the 2014 Regulations is applied to all registered providers of health and social care carrying on regulated activities under those Regulations (not just NHS providers) and it is the policy position is that it should be that duty which is applied via commissioning contracts as well. This ensures consistency across the provider sector in relation to candour, and means that any changes to the duty of candour in the 2014 Regulations will be reflected in the principal Regulations, without the principal Regulations needing to be changed as well.

Consolidation

- 7.14 The Department will consider consolidation of the principal Regulations over the longer term. A consolidated version of the principal Regulations may be obtained by contacting the Department of Health on the contact details mentioned in paragraph 13.

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 in respect of its commissioning functions.

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. As regards morbid obesity surgery services for adults, the Board will work with CCGs to support them in assuming commissioning responsibilities for these services.

10. Impact

- 10.1 The impact on business, charities or voluntary bodies is negligible.
- 10.2 Regulations 2 and 5 of these Regulations only change CCG responsibilities for after-care services, they do not impose additional burdens.
- 10.3 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 morbid obesity surgery services for adults 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.
- 10.4 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 activities that are undertaken by small businesses.

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 principal Regulations (which these Regulations amend) will be reviewed annually and updated as required.

13. Contact

- 13.1 Sarah Samuel at the Department of Health Telephone: 0113 254 6708 or email: sarah.samuel@dh.gsi.gov.uk can answer any queries regarding the instrument.