

EXPLANATORY MEMORANDUM TO
THE RESPONSIBILITIES AND STANDING RULES, AND CARE AND SUPPORT
(MISCELLANEOUS AMENDMENTS) REGULATIONS 2018

2018 No. 283

1. Introduction

- 1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

- 2.1 This instrument amends 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").
to:

- Update references to the NHS Continuing Care Fast Track Pathway Tool, National Framework for NHS Continuing Healthcare and NHS Funded Nursing Care ("the National Framework"), the NHS Continuing Healthcare Checklist and the Decision Support Tool for NHS Continuing Healthcare ("the Support Tools") which have been amended and republished;
- Amend the definitions of 'flat rate payment' and 'high band payments' to reflect the new rates for the provision of NHS Funded Nursing Care ("FNC") in relevant premises;
- Amend the definition of 'nursing care by a registered nurse';
- Amend the definition of 'regulated activity' to refer to the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014; and

- 2.2 Update the list of prescribed health services which the Board must commission for people with rare and very rare conditions
- 2.3 The instrument also amends the Care and Support (Provision of Health Services) Regulations 2014 and the Care and Support (Assessment) Regulations 2014 to reflect the updated and republished National Framework

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

- 3.1 The National Framework and Support Tools were published at 3pm on 1st March 2018, before the time at which this instrument was made at 5:30pm.

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

General Changes to Part 6 of the Principal Regulations

- 4.1 The term ‘regulated activity’ is used in the definition of ‘registered manager’, relevant premises’ and ‘service provider’ in Regulation 20 of the Principal Regulations. Regulation 20 defines the term regulated activity through reference to the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. These regulations have now been revoked and replaced by the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (the 2014 Regulations). This instrument updates the definition of ‘regulated activity’ to refer to the 2014 Regulations.

NHS Continuing Healthcare

- 4.2 NHS Continuing Healthcare (“CHC”) is provided by CCGs under sections 3 and 3A of the National Health Service Act 2006 (“2006 Act”)(duties and power of CCGs to commission certain health services), and by NHS England in respect of limited groups (including military and prisoners) under section 3B of the same Act (Secretary of State’s power to require NHS England to commission services).
- 4.3 CHC is defined in regulation 20 of the Principal Regulations as meaning “a package of care arranged and funded solely by the health service in England for a person aged 18 or over to meet physical or mental health needs which have arisen as a result of disability, accident or illness.” It is provided outside hospital, arranged and funded solely by the NHS, where it has been assessed that an individual has a ‘primary health need’
- 4.4 The concept of a primary health need was developed to assist in deciding which treatment and other health services it is appropriate for CCGs and NHS England to provide under sections 3, 3A or 3B as part of a CHC package. It also serves to distinguish between those and the services that Local Authorities (“LAs”) may provide under sections 18-20 of the Care Act 2014.
- 4.5 Regulation 21 sets out the duties of CCGs and NHS England in assessing and providing CHC.
- 4.6 In carrying out their duties in relation to CHC the Principal Regulations require that CCGs and NHS England use or have regard to specified documents. In particular regulation:
- 21(4)(a) requires organisations wishing to undertake an initial screening of an individual to decide whether to undertake an assessment of eligibility of CHC to use the NHS Continuing Healthcare Checklist (the Checklist);
 - 21(5)(a)(ii) requires that the Decision Support Tool for CHC must be completed as part of an assessment of eligibility for CHC;
 - 21(8) requires that where a decision to bypass the longer assessment process is made because the individual’s health is rapidly deteriorating or has entered the terminal phase the Fast Track Pathway Tool is completed; and
 - 21(12) requires that in carrying out their duties under the Principal Regulations organisations must have regard to the National Framework.
- 4.7 The Principal Regulations use the date of publication to identify National Framework and Support Tools. These documents have recently been reviewed and amended and updated versions will be published on 1st March 2018 for implementation on 1st

October 2018. This instrument amends the Principal Regulations to refer to the updated documents and these amending provisions come into force on 1st October 2018. This will give CCGs, NHS England and LAs time to prepare for the implementation of the National Framework and Support Tools which were published on 1st March 2018.

- 4.8 LAs also have duties in relation to CHC. Under regulation 4 of the Care and Support (Provision of Health Services) Regulations 2014, LAs are required to agree a dispute resolution procedure with CCGs and/or NHS England in relation to CHC and the Care and Support (Assessment) Regulations 2014 require LAs to refer an individual who they think may be eligible for CHC to a CCG or NHS England as applicable. Both sets of regulations require LAs to have regard to the National Framework which is identified by the date on which it was published. This instrument updates the reference to the National Framework to reflect the amended version published on 1st March 2018. These provisions also come into force on 1st October 2018, when the new version of the National Framework is implemented.

NHS Funded Nursing Care

- 4.9 The Principal Regulations also set out the duties of CCGs and NHS England in relation to FNC. In particular regulation 28 requires CCGs or NHS England as appropriate to undertake an assessment of an individual's eligibility for FNC if the organisation believes they may be eligible for nursing care and are resident or are going to be resident, in relevant premises (i.e. premises that are regulated by the Care Quality Commission and which have a registered manager). If an individual is, following assessment, found to be eligible for nursing care then regulation 28 further requires that the organisation pay the flat rate to the relevant premises for the provision of that individual's nursing care. Regulation 30 further sets out the circumstances under which the CCG or NHS England should make a high band payment for an individual's nursing care.
- 4.10 Regulation 20 currently defines nursing care as meaning nursing care by a registered nurse as defined by section 49(2) of the Health and Social Care Act 2001. This section has been revoked and has been replaced by the Care Act 2014, section 22(8). These Regulations therefore amend the definition of nursing care to refer to section 22(8) of the Care Act 2014.
- 4.11 Regulation 20 also defines the flat rate payment and high band payment through the amount which each payment represents. These are set annually by the Secretary of State. The new rates are due to come into force on the 1st April 2018 and these regulations amend the definitions to reflect the new rates.

Specialised Services

- 4.12 Section 3B of 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 7.16).

- 4.13 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 five new specialist services and amending the name of one other specialist service.
- 4.14 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 7.16), the Secretary of State has decided to make these amending Regulations.

5. Extent and Territorial Application

- 5.1 This instrument extends to England.
- 5.2 This instrument applies to England.

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

NHS Continuing Healthcare

- 7.1 CHC is a package of ongoing care provided outside hospital, arranged and funded solely by the NHS, where it has been assessed that an individual has a 'primary health need'. Services may be provided in any setting including, but not limited to, a residential care home, nursing home, hospice or a person's own home. If provided in a care home, it means that the NHS also makes a contract with the care home and pays the full fees for the person's accommodation, board and care.
- 7.2 Eligibility for CHC is not based on having a specific medical condition and eligibility places no limits on the settings in which the package of support can be offered or on the type of service delivery. The actual services provided as part of a package of CHC should be tailored to meet the specific needs of the individual.
- 7.3 There is thus no specific set of services that must constitute CHC. Services will depend on the needs of the individual in question and, whatever the services may be, people in receipt of CHC continue to be entitled, like other people, to the usual range of NHS primary, community, and secondary care, and other NHS services.
- 7.4 Following concerns about the local criteria used for making decisions about eligibility for CHC, and challenges to the legality of individual eligibility decisions in the Courts, in 2007 the Department of Health issued the National Framework.
- 7.5 The National Framework was first published in June 2007 and became mandatory from 1st October 2007. Instead of different NHS areas having their own rules for determining eligibility, the National Framework introduced a national approach for the NHS in England, with a common process and national tools to support decision

making (the Support Tools). The Secretary of State issued Directions requiring NHS bodies and LAs to comply with key aspects of the new policy.

- 7.6 Following the transfer of responsibility for CHC to CCGs in April 2013, the Principal Regulations set out CCG and NHS England duties in this area. In particular the regulations impose duties on CCGs in relation to both the National Framework and the Support Tools which are defined by reference to the date on which they were published - the 28th November 2012. LA duties in relation to CHC are also set out in legislation. These instruments also reference the National Framework defining it through the date on which it was published.
- 7.7 Feedback received since the National Framework and Support Tools were last amended in November 2012, is that there are areas of the National Framework and Support Tools that could be updated and clarified. In order to address these issues the Department has undertaken extensive engagement with stakeholders to look at potential amendments to the National Framework and the tools, in order to improve the operation of CHC. Key changes include:
- Setting out that the majority of CHC assessments should take place outside of acute settings. This will support accurate assessments of need and reduce unnecessary stays in hospital.
 - Additional advice for staff on when individuals do not need to be screened for CHC to reduce unnecessary assessment processes and respond to a call for greater clarity on this.
 - Clarifying the purpose of three and 12 month reviews to reduce unnecessary re-assessments which are a source of distress for patients.
 - Introducing new principles for how the local resolution process should run when individuals challenge an eligibility decision with the aim of resolving disputes earlier and more consistently.
 - Redrafting clearer sections on 'primary health need', the roles of CCGs and LAs, FNC, commissioning, top-ups and use of the Fast Track Pathway Tool for CHC.
- 7.8 Following this period of engagement with stakeholders and partners, the revised National Framework and Support Tools have been published. This instrument amends references to the National Framework and Support Tools in various pieces of legislation to refer to the latest versions. The amendments related to the National Framework and the Supporting Tools will come into force from 1st October 2018 which is the date agreed for the implementation of the revised documents.

NHS Funded Nursing Care

- 7.9 FNC, introduced in October 2001, is the funding provided by the NHS to care homes providing nursing, to support the provision of nursing care (as defined by the Principal Regulations) by a registered nurse, for those assessed as eligible. The Department meets this obligation by agreeing a national flat rate per person per week which is paid by CCGs. The Secretary of State sets the flat rate, which CCGs pay from their existing settlement.
- 7.10 The FNC rate effectively consists of two rates, the standard rate (referred to in the regulations as the 'flat rate payment') and the higher rate (referred to in the regulations as the 'high band payment'). Prior to the National Framework's introduction there had been three rates - low, medium and high. The flat rate payment

replaced the low and medium rates and the higher rate remained for those placed on this level before the change to the single band and whose needs were assessed as remaining high. There are very small numbers of people in receipt of the high band payment as they would have had to have continuous high level nursing needs since 2006.

- 7.11 The payments are reviewed annually usually taking account of increases to nursing wages and new rates are set. The regulations are amended to reflect the new rates which come into force on the 1st April of each year.
- 7.12 The definition of ‘nursing care’ used in the Principal Regulations is currently out of date as it refers to a statutory provision in the Health and Social Care Act 2001 which has been superseded by section 22(8) of the Care Act 2014 and this instrument updates the definition of ‘nursing care’ to refer to this section.

Specialised Services

- 7.13 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.
- 7.14 Although most services in the NHS 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”.
- 7.15 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 21st December 2017, and after having received advice from PSSAG, the Secretary of State 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 changes and the dates when they will come into force are:

- i. To add new services:

- a) Alpha 1 Antitrypsin services from 1st April 2019;
 - b) Gonadal Tissue Cryopreservation Services for children and young people at high risk of gonadal failure due to treatment or disease from 1st April 2020;
 - c) Psychological medicine inpatient services for severe and complex presentations of medically unexplained physical symptoms from 1st April 2020;
 - d) Specialist Adult Haematology services from 1st April 2020 and
 - e) Termination services where the expectant mother has significant comorbidities that require critical care and/or medical support from 1st April 2018.
- i. To change the wording of the following service:
- a) Amend ‘Specialist genetic services’ to ‘Clinical genomic services’ from 1st April 2018;

7.16 The Secretary of State, having obtained PSSAG’s advice, considers these changes appropriate, having regard to the four factors set out in section 3B(3) 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.

7.17 The Board does not currently commission the services listed at paragraph 7.15i, which are to be added to the list of services contained within Schedule 4 to the Principal Regulations. PSSAG has considered the proposals for these services to be nationally commissioned. PSSAG recommended, and ministers agreed, that these services met these four criteria.

7.18 With respect to the change in paragraph 7.15ii, PSSAG also considered a proposal for the Board to be the responsible commissioner of all clinical genomic testing services, rather than the most specialised, which are already commissioned by the Board. PSSAG recommended to Ministers that changing the scope of the service as outlined in paragraph 7.15ii meets the requirements for national commissioning with regard to the four statutory factors, and Ministers agreed. This will be reflected in Schedule 4 of the Principal Regulations by amending ‘Specialist genetic services’ to ‘Clinical genomic services,’ which will also better reflect how this evolving specialist services is described by the profession.

Consolidation

7.19 There are no plans to consolidate the regulations at this time.

8. Consultation outcome

NHS Continuing Healthcare

- 8.1 The amendments to the National Framework and other tools have been made following extensive engagement with interested parties.

NHS Funded Nursing Care

- 8.2 There is no statutory requirement to consult on the yearly amendment to the FNC rate, which is based on evidence of the costs of providing nursing care by a registered nurse, including uplifting for overall pay inflation.

Specialised Services

- 8.3 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 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 the services on the dates listed in paragraph 7.15. This allows time for the Board to appropriately prepare for the transfer of commissioning responsibility in each case.

9. Guidance

NHS Continuing Healthcare and NHS Funded Nursing Care

- 9.1 This legislation brings into force an updated National Framework and Support Tools which contain guidance for CCGs and NHS England on the assessment and provision of CHC. The amended documents have been published 7 months before they come into force to enable NHS England, CCGs, and LAs to prepare for their implementation. The National Framework also provides guidance on FNC.

Specialised Services

- 9.2 The Board publishes a number of documents explaining commissioning arrangements in this area, including 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, except Wednesdays when the line opens at the later time of 9.30am, and 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.

NHS Continuing Healthcare and NHS Funded Nursing Care

- 10.2 The impact on the NHS and LAs in their roles relating to CHC and FNC is expected to be positive. The updated National Framework is intended to improve the CHC and FNC process, and help CCGs and LAs undertake their duties in assessing individuals for CHC and FNC and commissioning services.
- 10.3 The FNC rate is amended each year in line with the best available evidence in order for the amount paid by the NHS for nursing care by a registered nurse to remain accurate. The FNC rate is increasing and therefore the NHS will pay an increased amount for FNC.

Specialised Services

- 10.4 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 marginally increase the range of services for which it has commissioning responsibility. 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.
- 10.5 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

NHS Continuing Healthcare and NHS Funded Nursing Care

- 12.1 The operation of the amended National Framework and Support Tools will be monitored and reviewed as part of the established National Policy Advisory Group for Continuing Healthcare
- 12.2 Rates for the provision of FNC in relevant premises are reviewed annually.

Specialised Services

- 12.3 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 2006 Act.
- 12.4 The Principal Regulations (which these Regulations amend) will be reviewed annually following the next PSSAG meeting and updated as required.

13. Contact

- 13.1 In relation to amendments concerning NHS Continuing Healthcare and NHS Funded Nursing Care, contact Colin Staniland at the Department of Health and Social Care, telephone: 0207 210 6232 or email: Colin.Staniland@dh.gsi.gov.uk, who can answer any queries those aspects of the instrument.
- 13.2 In relation to amendments concerning specialised services, contact Taina Miettinen at the Department of Health and Social Care, telephone: 020 7972 4978 or email:

Taina.Miettinen@dh.gsi.gov.uk, who can answer any queries regarding those aspects of the instrument.