

2012 No. 2996

MENTAL HEALTH, ENGLAND

NATIONAL HEALTH SERVICE, ENGLAND

The National Health Service
Commissioning Board and
Clinical Commissioning Groups
(Responsibilities and Standing
Rules) Regulations 2012

Made - - - -

3rd December 2012

Laid before Parliament

5th December 2012

Coming into force in accordance with regulation 1



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The Secretary of State for Health makes the following Regulations in exercise of the powers conferred by section 117(2E) and (2G) of the Mental Health Act 1983(a), sections 3(1B), 3A(3), 3B(1), 6E, 223E(3), 223J(3) and 272(7) and (8) of the National Health Service Act 2006(b) and section 75 of the Health and Social Care Act 2012(c).

Before deciding to make regulations under section 3B of the National Health Service Act 2006, the Secretary of State obtained appropriate advice and consulted the NHS Commissioning Board Authority in accordance with subsection (4) of that section(d).

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- (a) 1983 c.20. Subsections (2D) to (2G) were inserted by section 40(3) of the Health and Social Care Act 2012 (c. 7) (“the 2012 Act”).
- (b) 2006 c. 41. Subsections (1A) to (1E) of section 3 of the National Health Service Act 2006 (“the 2006 Act”) were inserted by section 13(3) of the 2012 Act. Section 3A was inserted by section 14 of the 2012 Act, section 3B was inserted by section 15 of that Act, section 6E was inserted by section 20 of that Act and sections 223E and 223J were inserted by sections 24 and 27 respectively of that Act. By virtue of section 271(1) of the 2006 Act, the powers exercised in making these Regulations are exercisable by the Secretary of State only in relation to England. See section 275(1) of the 2006 Act for the definitions of “prescribed” and “regulations”.
- (c) 2012 c.7.
- (d) See paragraph 2(1) of Schedule 6 to the 2012 Act which enables the requirement in section 3B(4) of the 2006 Act (as inserted by section 15 of the 2012 Act) for the Secretary of State to consult the National Health Service Commissioning Board (“the Board”) to be fulfilled if, before the commencement of section 9 of the 2012 Act, the Secretary of State consults a Special Health Authority. Before making these Regulations and the commencement of section 9 on 1st October 2012 (see S.I. 2012/1831), the Secretary of State consulted the NHS Commissioning Board Authority (“the Authority”), a Special Health Authority established under section 28 of the 2006 Act for the purpose of preparing for the establishment and operation of the Board. The Authority was established by the NHS Commissioning Board Authority (Establishment and Constitution) Order 2011 (S.I. 2011/2237) and is abolished by virtue of provision in Part 2 of the NHS Commissioning Board Authority (Abolition and Transfer of Staff, Property and Liabilities) and the Health and Social Care Act 2012 (Consequential Amendments) Order 2012 (S.I. 2012/1641).

PART 1

General

Citation and commencement

1.—(1) These Regulations may be cited as National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 and, subject to paragraphs (2) to (4), come into force on 1st April 2013.

(2) The following provisions of the Regulations come into force on 1st February 2013—

- (a) this Part;
- (b) Part 2 (persons for whom a CCG has responsibility);
- (c) Part 5 (standing rules: commissioning contract terms); and
- (d) insofar as they relate to the functions of a relevant body in arranging for the provision of services as part of the health service on and after the relevant date—
 - (i) Part 3 (services to be commissioned by the Board),
 - (ii) Part 4 (mental health after-care services),
 - (iii) in Part 6 (standing rules: NHS Continuing Healthcare and NHS funded nursing care), regulations 21, 22 and 28, and regulation 20 insofar as it defines terms that appear in those regulations,
 - (iv) in Part 7 (standing rules: decisions about drugs and other treatment), regulations 33 to 35,
 - (v) in Part 8 (standing rules: choice of health service provider), regulations 38 to 41,
 - (vi) in Part 9 (standing rules: waiting times), regulations 44 to 50 and 52 to 54, and
 - (vii) Part 10 (standing rules: funding of therapies for Multiple Sclerosis).

(3) Part 8 of these Regulations, insofar as the provisions of that Part are made under section 75 of the 2012 Act, comes into force immediately after that section comes fully into force(a).

(4) Part 11 of these Regulations (financial duties of a relevant body in relation to administration) comes into force immediately after sections 24 and 27 of the 2012 Act come fully into force(b).

Interpretation

2.—(1) In these Regulations—

“1983 Act” means the Mental Health Act 1983;

“the 2006 Act” means the National Health Service Act 2006;

“the 2012 Act” means the Health and Social Care Act 2012;

“armed forces” means the regular forces and the reserved forces within the meaning of the Armed Forces Act 2006(c);

“the Board” means the National Health Service Commissioning Board(d);

“CCG” means clinical commissioning group(e);

“commissioning contract” means a contract, other than a primary care contract, entered into by a relevant body in the exercise of its commissioning functions;

(a) Section 75 was commenced for limited purposes by section 306(1)(d) of the 2012 Act.

(b) Sections 24 and 27 were commenced for limited purposes by section 306(1)(d) of the 2012 Act and S.I. 2012/1831.

(c) 2006 c.52.

(d) The Board is established by section 1H of the 2006 Act as inserted by section 9(1) of the 2012 Act.

(e) A clinical commissioning group is a body established under section 14D of the 2006 Act. Section 14D is inserted by section 25(1) of the 2012 Act. *See also* section 11 of the 2006 Act, inserted by section 10 of the 2012 Act.

“commissioning functions” means the functions of a relevant body in arranging for the provision of services as part of the health service, but it does not include, in relation to the Board, its functions in relation to services provided under a primary care contract;

“consultant” means a person who has been appointed to a medical consultant post with a health service provider;

“general dental practitioner” means a person whose name is included in the register maintained by the General Dental Council under section 14 of the Dentists Act 1984(a);

“general medical practitioner” means a person registered in the General Practitioner Register held by the General Medical Council under section 34C of the Medical Act 1983(b);

“health care professional” means a member of a profession regulated by a body mentioned in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002(c);

“health care services” means one or more services consisting of the provision of treatment for the purposes of the health service;

“health service provider” means a person, other than a relevant body, who has entered into a commissioning contract;

“immigration removal centre” means a removal centre within the meaning of section 147 of the Immigration and Asylum Act 1999(d);

“maternity services” includes all services relating to female patients from the start of the pregnancy to 6 weeks after the birth other than—

- (a) the treatment of any medical condition unrelated to pregnancy,
- (b) the treatment of any medical condition which does not usually occur in the ordinary course of pregnancy, or
- (c) services relating to the termination of pregnancy in accordance with the Abortion Act 1967(e);

“mental health services” means services provided to patients in relation to a disorder or disability of the mind;

“optometrist” means a registered dispensing optician or a registered optometrist within the meaning of the Opticians Act 1989(f);

“patient” means any person who is receiving treatment provided as part of the health service;

“primary care contract” means a contract or other arrangement between the Board and a provider of primary care services to provide one or more primary care services;

“primary care services” means services provided as part of the health service pursuant to arrangements made by the Board under Parts 4 to 7 of the 2006 Act;

“relevant body” means a CCG or the Board;

“relevant date” means 1st April 2013;

“secure children’s home” means a children’s home used for the purpose of restricting liberty and approved for that purpose in respect of which a person is registered under Part 2 of the Care Standards Act 2000(g);

“secure training centre” means a place in which offenders subject to detention and training orders under section 100 of the Powers of Criminal Courts (Sentencing) Act 2000 (offenders

(a) 1984 c. 24.

(b) 1983 c. 54; section 34C was inserted by S.I. 2010/234.

(c) 2002 c. 17.

(d) 1999 c. 33. Relevant amendments were made by section 66(1) of the Nationality, Immigration and Asylum Act 2002 (c. 41).

(e) 1967 c.87.

(f) 1989 c.44. The definition of “optometrist” was inserted by S.I. 2005/848.

(g) 2000 c. 14.

under 18: detention and training orders)(a) may be detained and given training and education and prepared for their release;

“treatment”, except in Part 9 (waiting times), means an intervention that is intended to manage a person’s disease, condition or injury and includes prevention, examination and diagnosis;

“young offender institution” means a place for the detention of offenders sentenced to detention in a young offender institution or to custody for life.

(2) Except in Parts 2, 4 and 6, where reference is made in these Regulations to a person or persons for whom the relevant body has responsibility, or to a person whom the relevant body is responsible for, it means—

- (a) in respect of a CCG, a person for whom it is responsible under or by virtue of section 3 of the 2006 Act (duties of clinical commissioning groups as to commissioning certain health services)(b), in relation only to the provision of services which it has a duty to arrange for, or in respect of, that person; and
- (b) in respect of the Board, a person for or in respect of whom it is required to arrange the provision of services for under or by virtue of regulations under section 3B of the 2006 Act (Secretary of State’s power to require Board to commission services), in respect only of services which the Board is required to arrange for, or in respect of, that person.

PART 2

Persons for whom a CCG has responsibility

Interpretation of Part 2

3. In this Part, “walk-in centre” means a centre at which information and treatment for minor conditions is provided to the public under arrangements made by a relevant body.

Additional persons for whom a CCG has responsibility

4.—(1) Subject to paragraphs (2) to (4), for the purposes of sections 3 and 3A of the 2006 Act (which relate respectively to a CCG’s duty to commission services and its power to do so), a CCG has responsibility for the persons listed in paragraph 2 of Schedule 1 (in addition to those mentioned in section 3(1A) of that Act).

(2) In the case of a person listed in paragraph 2(a), (b), (d), (e) or (f) of Schedule 1, a CCG has responsibility only in relation to the provision of accommodation or services specified in the subparagraph of paragraph 2 which relates to that person.

(3) The responsibility for a person listed in paragraph 2(c), (g), (h), (i) or (j) of Schedule 1, does not apply in relation to the provision of ambulance services or accident and emergency services, whether provided at a hospital accident and emergency department, a minor injuries unit, a walk-in centre or elsewhere (but excluding any services provided after the person has been accepted as an in-patient, or at an out-patient appointment).

(4) The responsibility for persons listed in paragraph 2(b) to (j) of Schedule 1 does not apply where the person is detained in—

- (a) an immigration removal centre;
- (b) a secure training centre; or
- (c) a young offender institution.

(a) 2000 c. 6. Section 100 was amended by paragraph 184 of Schedule 7 to the Criminal Justice and Court Services Act 2000 (c. 43), by paragraph 111 of Schedule 32 to the Criminal Justice Act 2003 (c. 44), and by paragraph 11 of Schedule 26 and paragraph 13 of Schedule 21 to the Legal Aid, Sentencing and Punishment of Offenders Act 2012 (c. 10).

(b) See Part 2 of these Regulations as to persons for whom a CCG has responsibility.

PART 3

Services to be commissioned by the Board

Interpretation of Part 3

5. In this Part—

“Armed Forces Compensation Scheme” means the Armed Forces and Reserve Forces Compensation Scheme 2011 set out in the Armed Forces and Reserve Forces (Compensation Scheme) Order 2011^(a);

“community dental services” means dental services provided as part of the health service other than—

- (a) emergency services,
- (b) dental services provided pursuant to arrangements made by the Board under Part 5 of the 2006 Act, or
- (c) the dental services specified in Schedule 2;

“community services” means services provided as part of the health service other than—

- (a) emergency services,
- (b) primary care services,
- (c) secondary care services, or
- (d) the services specified in Schedule 4;

“Defence Medical Services” means medical services provided by—

- (a) the Ministry of Defence including the Surgeon General’s organisation,
- (b) other elements of the Joint Forces Command, and
- (c) the three single Service medical organisations^(b);

“emergency services” means ambulance services and accident and emergency services provided as part of the health service, whether provided at a hospital accident or emergency department, a minor injuries unit, a walk-in centre or elsewhere;

“secondary care services” means services provided as part of the health service in a hospital setting, or by those working in or based in a hospital setting, other than emergency services, primary care services or the services specified in Schedule 4;

“veteran” means any person who has served for at least one day in one of the armed forces or Merchant Navy seafarers and fishermen who have served in a vessel at a time when it was operated to facilitate military operations by the armed forces.

Dental services

6. The Board must arrange, to such extent as it considers necessary to meet all reasonable requirements, for the provision as part of the health service of—

- (a) community dental services; and
- (b) the dental services specified in Schedule 2.

Services for serving members of the armed forces and their families

7.—(1) This regulation applies to—

- (a) a person who is a serving member of the armed forces; and

^(a) S.I. 2011/517.

^(b) The three single Service organisations referred to are Royal Navy Medical Services, Army Medical Services and RAF Medical Services.

(b) that person's family.

(2) The Board must arrange, to such extent as it considers necessary to meet all reasonable requirements, for the provision as part of the health service to persons to whom this regulation applies of—

- (a) community services;
- (b) secondary care services; and
- (c) the services specified in Schedule 4.

(3) The arrangements to be made by the Board under paragraph (2)(b) in respect of a person referred to in paragraph (1)(a) must include the provision of any infertility treatment to that person and to that person's partner.

(4) The infertility treatment referred to in paragraph (3) must—

- (a) where a person referred to in paragraph (1)(a) has been injured in service and is in receipt of compensation for infertility under the Armed Forces Compensation Scheme, include funding the cost of sperm storage facilities from the date on which the injury was sustained (where clinically necessary and where provision for such storage has previously been made); and
- (b) where, and to the extent that, the Board is satisfied that this is clinically appropriate in the circumstances of any case, include the provision of up to three cycles of in vitro fertilisation treatments or other means of assisted conception.

(5) In paragraph (1)(b), "family", in relation to a person to whom this regulation applies, means that person's immediate family registered for primary care services with Defence Medical Services.

(6) The Board must regard a person ("A") as the partner of a person referred to in paragraph (1)(a) ("B") if—

- (a) A is the spouse or civil partner of B; or
- (b) A and B are cohabiting as partners in a substantial and exclusive relationship in circumstances where either—
 - (i) A is financially dependent on B, or
 - (ii) A and B are financially interdependent.

(7) In deciding whether A is in a substantial relationship with B, the Board must—

- (a) have regard to any evidence which A considers demonstrates that the relationship is substantial; and
- (b) in particular, have regard to the examples of evidence specified in paragraph (8) which could, either alone or together, indicate that the relationship is substantial.

(8) The evidence referred to in paragraph (7)(b) is—

- (a) evidence of regular financial support of A by B;
- (b) evidence of a will or life insurance policy, valid at the time at which the infertility treatment is sought in which—
 - (i) B nominates A as principal beneficiary or co-beneficiary, or
 - (ii) A nominates B as the principal beneficiary;
- (c) evidence indicating that A and B have purchased or are purchasing accommodation together as joint owners or evidence of joint ownership of other valuable property, such as a car or land;
- (d) evidence of a joint savings plan or joint investments of a substantial nature;
- (e) evidence that A and B operate a joint account for which they are co-signatories;
- (f) evidence of joint financial arrangements such as joint repayment of a loan or payment of each other's debts;
- (g) evidence that either A or B has given the other the power of attorney;

- (h) evidence that the names of both A and B appear on a lease or, if they live in rental accommodation, rental agreement; and
- (i) evidence of the length of the relationship.

(9) For the purposes of paragraph (6)(b), a relationship is not an exclusive relationship if one or both of the parties is a party to another relationship which is, or could be considered to be, a substantial and exclusive relationship having regard to the provisions of this regulation.

Infertility treatment: seriously injured serving members and veterans

8.—(1) This regulation applies to a person who is a serving member of the armed forces or a veteran of the armed forces where that person—

- (a) has been severely injured in service; and
- (b) as a result of the injury sustained—
 - (i) suffers from infertility, and
 - (ii) is in receipt of compensation for infertility under the Armed Forces Compensation Scheme; and
- (c) after specialist sperm retrieval, wishes to receive infertility treatment and is eligible for, and has been accepted for, such treatment.

(2) The Board must arrange, to such extent as it considers necessary to meet all reasonable requirements, for the provision as part of the health service of infertility treatment to a person to whom this regulation applies and to that person’s partner.

(3) The infertility treatment referred to in paragraph (2) must—

- (a) in any case, include funding the cost of sperm storage facilities;
- (b) where, and to the extent that, the Board is satisfied that it is clinically appropriate in the circumstances of any particular case, include up to three cycles of in vitro fertilisation treatments or other means of assisted conception;
- (c) be provided at the same facility at which the specialist sperm retrieval took place and the extracted sperm of that person is stored.

(4) For the purposes of this regulation and regulation 9, “partner” is to be construed in accordance with regulation 7(6) to (9).

Infertility treatment: further provision

9.—(1) Where a person referred to in regulation 7(1)(a) or 8(1)—

- (a) has died or has become mentally incapacitated; and
- (b) has, before the time of that person’s death or mental incapacity—
 - (i) made provision for sperm storage, and
 - (ii) given written consent to the stored sperm being used by a named partner,

the Board must arrange, to such extent as it considers necessary to meet all reasonable requirements, for the provision as part of the health service of infertility treatment to that person’s named partner.

(2) The infertility treatment referred to in paragraph (1) must—

- (a) in any case, include funding the cost of sperm storage facilities from the date on which the person died or, as the case may be, became mentally incapacitated; and
- (b) where, and to the extent that, the Board is satisfied that it is clinically appropriate in the circumstances of any particular case, include up to three cycles of in vitro fertilisation treatments and other means of assisted conception.

(3) Where infertility treatment is provided by the Board under paragraph (1) to the named partner of a person referred to in regulation 8(1), that treatment must be provided at the same

facility at which specialist sperm retrieval took place in relation to that person and at which that person's extracted sperm has been stored.

Services for prisoners and other detainees

10.—(1) Where a person is detained in a prison or in other accommodation described in paragraph (2), the Board must arrange, to such extent as it considers necessary to meet all reasonable requirements, for the provision to that person as part of the health service of—

- (a) community services;
- (b) secondary care services; and
- (c) the services specified in Schedule 4.

(2) The other accommodation referred to in paragraph (1) is—

- (a) a court;
- (b) a secure children's home (except those specified in Part 1 of Schedule 3);
- (c) a secure training centre specified in the first column of Table 1 in Schedule 3 from the date specified in the corresponding entry in the second column of that Table;
- (d) an immigration removal centre specified in the first column of Table 2 in Schedule 3 from the date specified in the corresponding entry in the second column of that Table; and
- (e) a young offender institution (except Ashfield Young Offender Institution).

(3) In this regulation, "court" means any court in which criminal proceedings against a person are heard.

Specified services for rare and very rare conditions

11. The Board must arrange, to such extent as it considers necessary to meet all reasonable requirements, for the provision as part of the health service of the services specified in Schedule 4.

Assessment, diagnostic, elective and minor elective care services provided by Independent Sector Treatment Centres

12.—(1) This regulation applies to services provided by an Independent Sector Treatment Centre pursuant to the arrangements specified in paragraph (2).

(2) The arrangements referred to in paragraph (1) are—

- (a) the agreement made on 20th July 2005 and ending on 27th July 2013 between the Secretary of State for Health, Nations Healthcare (Nottingham) Limited, Nottinghamshire County Teaching Primary Care Trust, Nottingham City Primary Care Trust, Derby City Primary Care Trust, Derbyshire County Primary Care Trust, Lincolnshire Teaching Primary Care Trust, Leicestershire County and Rutland Primary Care Trust, Bassetlaw Primary Care Trust and Nottinghamshire University Hospitals NHS Trust for the provision of elective services and diagnostic services by Nations Healthcare (Nottingham) Limited;
- (b) the agreement made on 15th December 2006 and ending on 31st March 2014 between the Secretary of State for Health, InHealth Group Limited and InHealth London Limited for the provision of diagnostic services by InHealth London Limited;
- (c) the agreement made on 30th May 2008 and ending on 2nd February 2016 between the Secretary of State for Health, Care UK Clinical Services Limited and Care UK Limited for the provision of assessment and minor elective care services and diagnostic services by Care UK Clinical Services Limited;
- (d) the agreement made on 30th May 2008 and ending on 27th October 2015 between the Secretary of State for Health, PHG (Hampshire) Limited and Care UK plc for the provision of elective services and diagnostic services by PHG (Hampshire) Limited;

- (e) the agreement made on 31st July 2008 and ending on 31st October 2015 between the Secretary of State for Health, UKSH South West Limited and UK Specialist Hospitals Limited for the provision of elective services and diagnostic services by UKSH South West Limited; and
- (f) the agreement made on 26th September 2011 and ending on 16th October 2016 between the Secretary of State for Health, Clinicenta (Hertfordshire) Limited and Carillion plc for the provision of elective services and assessment and minor elective care services by Clinicenta (Hertfordshire) Limited.

(3) The Board must arrange, to such extent as it considers necessary to meet all reasonable requirements, for the provision as part of the health service of the services to which each of the agreements specified in paragraph (2)(a) to (f) relates for the period beginning on 1st April 2013 and, in the case of each respective agreement, ending on the date on which that agreement comes to an end.

(4) In this regulation—

“assessment and minor elective care services” means services related to the assessment, screening and planned care or treatment of minor medical conditions;

“diagnostic services” includes imaging services (such as MRI, CT, Ultrasound, Xray, Dexa Scan), physiological measurement, audiology, endoscopies, including direct access diagnostic services from primary care and other ancillary services needed to support the delivery of these services; and

“elective services” means clinical care services including Final Finished Consultant Episodes relating to, for example, trauma and orthopaedic surgery, general surgery, ear nose and throat, oral surgery, urology, gynaecology, plastic surgery, ophthalmology, hepatobiliary and pancreatic surgery, colorectal surgery, vascular surgery, gastroenterology, respiratory medicine, endocrinology, rheumatology, pain management and dermatology.

Fixated threat assessment services

13.—(1) The Board must arrange, to such extent as it considers necessary to meet all reasonable requirements, for the provision as part of the health service of specialised clinical risk assessment and management services for people with mental health problems who may present a risk to prominent people or locations.

(2) The arrangements to be made by the Board under paragraph (1) must include—

- (a) the provision of funding for mental health staff to provide the services referred to in paragraph (1); and
- (b) such provision for partnership working with other persons or health services as is considered necessary to facilitate the effective delivery of those services.

PART 4

Mental health after-care services

Circumstances in which duty may be imposed on another CCG

14.—(1) The duty imposed by subsection (2) of section 117 of the 1983 Act on a CCG(a) (CCG A) to arrange for the provision of after-care services for a person (P) to whom section 117 applies is to be imposed instead on another CCG (CCG B) in the circumstances below.

(2) These circumstances are where CCG B has responsibility for P by virtue of—

- (a) section 3(1A) of the 2006 Act(b); or

(a) Section 117(2) of the 1983 Act was amended by sections 40(1) and (2)(a) of the 2012 Act.

(b) Section 3(1A) was inserted by section 13(3) of the 2012 Act.

- (b) regulation 4 of, and sub-paragraph (c), (g), (h), (i) or (j) of paragraph 2 of Schedule 1 to these Regulations.

Circumstances in which duty may be imposed on the Board

15.—(1) The duty imposed by subsection (2) of section 117 of the 1983 Act on a CCG to arrange for the provision of after-care services for a person (P) to whom section 117 of the 1983 Act applies is to be imposed instead on the Board in the circumstances below.

(2) These circumstances are where P is receiving an after-care service under section 117 which, if it were being provided under the 2006 Act, would be a service whose provision the Board had a duty to arrange.

PART 5

Standing rules: commissioning contract terms

Matters to be included in commissioning contracts

16.—(1) A commissioning contract entered into by a relevant body must contain terms and conditions that prescribe the circumstances in which the health service provider must provide to a relevant person—

- (a) an appropriate apology; and
- (b) the relevant information,

where there has been a patient safety incident.

(2) In this regulation—

“appropriate apology” means a sincere expression of sorrow or regret, given in writing, for the harm that has resulted from a patient safety incident;

“patient safety incident” means an unintended or unexpected incident that occurs in respect of a patient, during and as a result of the provision of health care services, that could have led to, or did lead to, harm to that patient;

“relevant person” means the patient in respect of whom the patient safety incident occurred, or someone lawfully acting on that patient’s behalf;

“relevant information”, in relation to a patient safety incident, means written details of—

- (a) the patient safety incident,
- (b) any investigation that has been carried out into that incident, and any causes of that incident, or other findings, that have been identified as a result of such an investigation, and
- (c) any steps that have been taken to prevent the recurrence of such an incident.

Terms and conditions to be drafted by the Board

17.—(1) The Board must draft—

- (a) terms and conditions making provision for the matters specified in regulation 16; and
- (b) such other terms and conditions as the Board considers are, or might be, appropriate for inclusion in commissioning contracts entered into by a relevant body.

(2) The Board may draft model commissioning contracts which reflect the terms and conditions it has drafted pursuant to paragraph (1).

(3) A relevant body must incorporate the terms and conditions drafted by virtue of paragraph (1)(a) in commissioning contracts entered into by it.

(4) The Board may require CCGs to incorporate the terms and conditions it has drafted pursuant to paragraph (1)(b) in commissioning contracts that a CCG enters into.

(5) If a CCG is required by the Board to incorporate terms and conditions pursuant to paragraph (4), it must do so.

Consultation by the Board

- 18.**—(1) The Board must consult the persons specified in paragraph (2)—
- (a) before exercising its functions under regulation 17(1) and (2) for the first time; and
 - (b) before revising—
 - (i) terms and conditions it has drafted pursuant to regulation 17(1), or
 - (ii) a model commissioning contract it has drafted pursuant to regulation 17(2), in a way which would, in the opinion of the Board, result in a substantial change to those terms and conditions or that contract (as the case may be).
- (2) The persons specified for the purposes of paragraph (1) are—
- (a) the Care Quality Commission(a);
 - (b) CCGs;
 - (c) Healthwatch England(b);
 - (d) Monitor(c);
 - (e) the Secretary of State; and
 - (f) such other persons as the Board considers it is appropriate to consult.

Transitional provision

19.—(1) The requirements in regulations 16 and 17 apply in relation to commissioning contracts entered into on or after 1st February 2013.

(2) Consultation undertaken before the coming into force of this Part is as effective for the purposes of regulation 18 as consultation undertaken after the coming into force of this Part.

PART 6

Standing rules: NHS Continuing Healthcare and NHS funded nursing care

Interpretation

- 20.**—(1) In this Part—
- “2008 Act” means the Health and Social Care Act 2008(d);
 - “Fast Track Pathway Tool” means the Fast Track Pathway Tool for NHS Continuing Healthcare issued by the Secretary of State and dated 28th November 2012(e);
 - “flat rate payment” means a payment of £108.70 per week;
 - “high band payment” means a payment made at the high band rate of £149.60 per week following a RNCC determination;
 - “low band payment” means a payment made at the low band rate following a RNCC determination;

(a) The Care Quality Commission is established by section 1 of the Health and Social Care Act 2008 (c. 14) (“the 2008 Act”).

(b) Healthwatch England is established as a committee of the Care Quality Commission by virtue of paragraph 6(1A) of Schedule 1 to the 2008 Act, as amended by section 181(2) of the 2012 Act.

(c) Monitor is the new name given to the Independent Regulator of NHS Foundation Trusts: *see* section 61 of the 2012 Act.

(d) 2008 c. 14.

(e) The Fast Track Pathway Tool can be found at www.dh.gov.uk/health/2012/11/continuing-healthcare-revisions/.

“medium band payment” means a payment made at the medium band rate following a RNCC determination;

“National Framework” means the National Framework for NHS Continuing Healthcare and NHS-funded Nursing Care issued by the Secretary of State and dated 28th November 2012(a);

“NHS Continuing Healthcare” means 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;

“nursing care” means nursing care by a registered nurse and “nursing care by a registered nurse” has the same meaning as in section 49(2) of the Health and Social Care Act 2001(b);

“old Guidance” means the documents entitled “Guidance on Free Nursing Care in Nursing Homes” dated 25th September 2001(c) and “NHS Funded Nursing Care Practice Guidance and Workbook (August 2001)” dated 5th September 2001(d), as supplemented by “NHS Continuing Health Care: Action following the Grogan Judgement” dated 3rd March 2006(e);

“registered manager” means, in respect of relevant premises, a person registered with the Care Quality Commission under Chapter 2 of Part 1 of the 2008 Act as a manager in respect of the regulated activity carried on at those premises;

“registered person” means, in respect of relevant premises, a person who is a service provider or registered manager in respect of those premises;

“regulated activity” means the activity of providing residential accommodation, together with personal or nursing care, specified in paragraph 2 of Schedule 1 to the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010(f);

“relevant premises” means premises where regulated activity is carried on and for which there is a registered person;

“relevant social services authority” means the social services authority appearing to a relevant body to be the authority in whose area a patient is ordinarily resident;

“RNCC determination” means a determination as to the Registered Nursing Contribution to Care taken in respect of a person in accordance with the National Health Service (Nursing Care in Residential Accommodation) (England) Directions 2001(g);

“service provider” means, in respect of relevant premises, a person registered with the Care Quality Commission under Chapter 2 of Part 1 of the 2008 Act as a service provider in respect of the regulated activity carried on at those premises;

“social services authority” means a local authority for the purposes of the Local Authority Social Services Act 1970(h) and the Council of the Isles of Scilly;

“social services authority area” means an area for which a local social services authority is responsible.

(2) For the purposes of this Part a relevant body has responsibility for a person if the body is responsible—

(a) in the case of a CCG, by virtue of—

(a) The National Framework for NHS Continuing Healthcare and NHS-funded Nursing Care can be found at www.dh.gov.uk/health/2012/11/continuing-healthcare-revisions/.

(b) 2001 c. 15.

(c) The guidance can be found at www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthservicecirculars/DH_4003954.

(d) The guidance and workbook can be found at webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4009471.

(e) The guidance can be found at www.dh.gov.uk/en/Publicationsandstatistics/Publications/Publicationspolicyandguidance/DH_4131162.

(f) S.I. 2010/781. Paragraph 2 of Schedule 1 has been amended by article 2 of, and paragraph 27 of the Schedule to, S.I. 2012/979.

(g) The Directions can be found at www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_4003016.

(h) 1970 c.42. See section 1, to which a relevant amendment was made by section 195(3) of the Local Government Act 1972 (c. 70).

- (i) section 3(1A) of the 2006 Act, except where the person is a person for whom another CCG is responsible by virtue of paragraph 2(b), (d), (e) or (f) of Schedule 1 to these Regulations, or
 - (ii) paragraph 2, other than paragraph 2(a), of Schedule 1 to these Regulations; or
- (b) in the case of the Board, by virtue of regulation 7 (secondary care services and community services: serving members of the armed forces and their families) or regulation 10 (services for prisoners and other detainees).

(3) For the purposes of this Part, an assessment in relation to a person's need for nursing care means such assessment as the relevant body considers appropriate in the circumstances in order to determine whether the person has a need for nursing care.

Duty of relevant bodies: assessment and provision of NHS Continuing Healthcare

21.—(1) In exercising its functions under or by virtue of sections 3, 3A or 3B of the 2006 Act, insofar as they relate to NHS Continuing Healthcare, a relevant body must comply with paragraphs (2) to (11).

(2) A relevant body must take reasonable steps to ensure that an assessment of eligibility for NHS Continuing Healthcare is carried out in respect of a person for which that body has responsibility in all cases where it appears to that body that—

- (a) there may be a need for such care; or
- (b) an individual who is receiving NHS Continuing Healthcare may no longer be eligible for such care.

(3) If an assessment for NHS Continuing Healthcare is required under paragraph (2)(a), the relevant body must ensure that it is carried out before any assessment pursuant to regulation 28(1) (persons who enter relevant premises or who develop a need for nursing care) is carried out.

(4) If a relevant body wishes to use an initial screening process to decide whether to undertake an assessment of a person's eligibility for NHS Continuing Healthcare it must—

- (a) complete and use the NHS Continuing Healthcare Checklist issued by the Secretary of State and dated 28th November 2012^(a) to inform that decision;
- (b) inform that person (or someone lawfully acting on that person's behalf) in writing of the decision as to whether to carry out an assessment of that person's eligibility for NHS Continuing Healthcare; and
- (c) make a record of that decision.

(5) When carrying out an assessment of eligibility for NHS Continuing Healthcare, a relevant body must ensure that—

- (a) a multi-disciplinary team—
 - (i) undertakes an assessment of needs, or has undertaken an assessment of needs, that is an accurate reflection of that person's needs at the date of the assessment of eligibility for NHS Continuing Healthcare, and
 - (ii) uses that assessment of needs to complete the Decision Support Tool for NHS Continuing Healthcare issued by the Secretary of State and dated 28th November 2012^(b); and
- (b) the relevant body makes a decision as to whether that person has a primary health need in accordance with paragraph (7), using the completed Decision Support Tool to inform that decision.

(6) If a relevant body decides that a person has a primary health need in accordance with paragraph (5)(b), it must also decide that that person is eligible for NHS Continuing Healthcare.

(a) The NHS Continuing Healthcare Checklist can be found at www.dh.gov.uk/health/2012/11/continuing-healthcare-revisions/.

(b) The Decision Support Tool can be found at www.dh.gov.uk/health/2012/11/continuing-healthcare-revisions/.

(7) In deciding whether a person has a primary health need in accordance with paragraph (5)(b), a relevant body must consider whether the nursing or other health services required by that person are—

- (a) where that person is, or is to be, accommodated in relevant premises, more than incidental or ancillary to the provision of accommodation which a social services authority is, or would be but for a person's means, under a duty to provide; or
- (b) of a nature beyond which a social services authority whose primary responsibility is to provide social services could be expected to provide,

and, if it decides that the nursing or other health services required do, when considered in their totality, fall within sub-paragraph (a) or (b), it must decide that that person has a primary health need.

(8) Paragraphs (2) to (6) do not apply where an appropriate clinician decides that—

- (a) an individual has a primary health need arising from a rapidly deteriorating condition; and
- (b) the condition may be entering a terminal phase,

and that clinician has completed a Fast Track Pathway Tool stating reasons for the decision.

(9) A relevant body must, upon receipt of a Fast Track Pathway tool completed in accordance with paragraph (8), decide that a person is eligible for NHS Continuing Healthcare.

(10) Where an assessment of eligibility for NHS Continuing Healthcare has been carried out, or a relevant body has received a Fast Track Pathway Tool completed in accordance with paragraph (8), the relevant body must—

- (a) notify the person assessed (or someone lawfully acting on that person's behalf), in writing, of the decision made about their eligibility for NHS Continuing Healthcare, the reasons for that decision and, where applicable, the matters referred to in paragraph (11); and
- (b) make a record of that decision.

(11) Where a relevant body has decided that a person is not eligible for NHS Continuing Healthcare, it must inform the person (or someone acting on that person's behalf) of the circumstances and manner in which that person may apply for a review of the decision if they are dissatisfied with—

- (a) the procedure followed by the relevant body in reaching that decision; or
- (b) the primary health need decision made in accordance with paragraph (5)(b).

(12) In carrying out its duties under this regulation, a relevant body must have regard to the National Framework.

(13) In this regulation—

“appropriate clinician” means a person who is—

- (a) responsible for the diagnosis, treatment or care of the person under the 2006 Act in respect of whom a Fast Track Pathway Tool is being completed, and
- (b) a registered nurse^(a) or a registered medical practitioner^(b);

“healthcare profession” means a profession which is concerned (wholly or partly) with the physical or mental health of individuals (whether or not that person is regulated by, or by virtue of, any enactment);

“multi-disciplinary team” means a team consisting of at least—

- (a) two professionals who are from different healthcare professions, or

(a) See Schedule 1 of the Interpretation Act 1978 (c. 3) for the definition of a registered nurse.

(b) See Schedule 1 of the Interpretation Act 1978 (c. 3) for the definition of a registered medical practitioner.

- (b) one professional who is from a healthcare profession and one person who is responsible for assessing persons for community care services under section 47 of the National Health Service and Community Care Act 1990(a).

Duty of relevant bodies: joint working with social services authorities

22.—(1) A relevant body must, insofar as is reasonably practicable—

- (a) consult with the relevant social services authority before making a decision about a person’s eligibility for NHS Continuing Healthcare, including any decision that a person receiving NHS Continuing Healthcare is no longer eligible to do so; and
- (b) co-operate with the relevant social services authority in arranging for persons to participate in a multi-disciplinary team for the purpose of fulfilling its duty under regulation 21(5).

(2) Where there is a dispute between a relevant body and the relevant social services authority about—

- (a) a decision as to eligibility for NHS Continuing Healthcare; or
- (b) where a person is not eligible for NHS Continuing Healthcare, the contribution of a relevant body or social services authority to a joint package of care for that person,

the relevant body must, having regard to the National Framework, agree a dispute resolution procedure with the relevant social services authority, and resolve the disagreement in accordance with that procedure.

(3) In complying with its duties under regulation 21 and this regulation, a relevant body must have due regard to the need to promote and secure the continuity of appropriate services for persons who—

- (a) are receiving community care services under section 47 of the National Health Service and Community Care Act 1990 on the date on which they are found to be eligible to receive NHS Continuing Healthcare;
- (b) have been in receipt of NHS Continuing Healthcare but are determined to be no longer eligible for NHS Continuing Healthcare; or
- (c) are otherwise determined to be ineligible for NHS Continuing Healthcare.

The Board’s duty: reviewing decisions

23.—(1) The Board must—

- (a) appoint such number of persons to act as chairs of the panels referred to in paragraph (4) (“chairs”) as the Board considers reasonable to ensure that applications for a review under paragraph (3) can be considered by such a panel within a reasonable time; and
- (b) establish a list consisting of the following persons—
 - (i) at least one person (“a CCG member”) appointed by the Board in respect of each CCG, and
 - (ii) at least one person (“a social services authority member”) appointed by the Board in respect of each social services authority.

(2) In complying with its duty under paragraph (1), the Board must ensure that the persons it—

- (a) appoints under paragraph (1)(a); or
- (b) includes in a list pursuant to paragraph (1)(b),

(a) 1990 c. 19; section 47 has been amended by the Health Authorities Act 1995 (c. 17), Schedule 1, paragraph 81; the National Health Service Reform and Health Care Professions Act 2002 (c. 17), Schedule 2, paragraph 56; the National Health Service (Consequential Provisions) Act 2006 (c. 43), Schedule 1, paragraph 130; and the 2012 Act, Schedule 5, paragraph 59.

reside in locations that have a sufficient geographical distribution to ensure that a review panel can be held in any social services authority area in England.

- (3) Where a person, or someone lawfully acting on a person's behalf—
- (a) is dissatisfied with—
 - (i) the procedure followed by a relevant body in reaching a decision as to that person's eligibility for NHS Continuing Healthcare pursuant to regulation 21(5), or
 - (ii) the primary health need decision by a relevant body pursuant to regulation 21(5)(b); and
 - (b) the person has—
 - (i) used the resolution procedure of the relevant body in question, but that has not resolved the matter, or
 - (ii) not used that resolution procedure and the Board is satisfied that requiring the person to do so would cause undue delay,

that person may apply in writing to the Board for a review of that decision.

(4) Following receipt of an application for a review under paragraph (3), the Board may refer the matter for a decision to a panel of members ("a review panel") consisting of—

- (a) a chair;
- (b) one CCG member drawn from the list established under paragraph (1)(b) who has been appointed in respect of a CCG, other than a CCG whose procedure or decision is the subject of the review; and
- (c) one social services authority member drawn from that list who has been appointed in respect of a social services authority other than one in whose area is situated all or part of the area of a CCG whose procedure or decision is the subject of the review.

(5) Where an application for a review under paragraph (3) relates to the procedure followed by, or a decision taken by, the Board, it must ensure that in organising a review of that decision, it makes appropriate arrangements as regards the manner in which it organises such a review so as to avoid any conflict of interest.

(6) The procedure and operation of the review panel are to be a matter for the chair of the review panel, having regard to the National Framework.

(7) The Board must, as soon as reasonably practicable, give notice in writing of the review decision and the reasons for it to the applicant and, where the relevant body is a CCG, to the CCG whose decision has been the subject of review.

(8) A relevant body must, unless it determines in accordance with paragraph (9) that there are exceptional reasons not to do so, implement the decision of the review panel as soon as reasonably practicable.

(9) In determining whether under paragraph (8) there are exceptional reasons, a relevant body must have regard to the National Framework.

Appointment and term of appointment

24.—(1) Subject to regulation 25 (disqualification for appointment), the CCG members and social services authority members must be appointed by the Board following nomination by a CCG or a social services authority in respect of which they are to be appointed.

- (2) A CCG must—
- (a) when requested to do so by the Board, provide its nomination pursuant to paragraph (1) as soon as is reasonably practicable; and
 - (b) ensure that CCG members are, so far as reasonably practicable, available to participate in review panels.

(3) Subject to regulation 27 (termination of appointment), the term of appointment of a chair, a CCG member or a social services authority member is to be such period, not exceeding three years, as the Board specifies on making the appointment.

(4) Subject to regulation 25 (disqualification for appointment), a chair, CCG member or social services authority member is to be eligible for reappointment on the termination of the period of that chair or member's term of appointment.

(5) The Board must pay to a chair such remuneration and expenses as appear to it to be reasonable.

Disqualification for appointment

25.—(1) A person is disqualified for appointment as a chair if that person is—

- (a) the chair, a member (other than a member of an NHS foundation trust), a director, a governor or an employee of an NHS body;
- (b) the chair or a member of the governing body of a CCG; or
- (c) an elected member or employee of a social services authority in England and Wales or of an equivalent body in Scotland or Northern Ireland.

(2) A person is disqualified for appointment as a CCG member or social services authority member if that person is—

- (a) the chair, the chief executive, a non-executive director or a non-officer member of an NHS body (other than a member of an NHS foundation trust);
- (b) the chair or a member of the governing body of a CCG; or
- (c) an elected member of a social services authority in England and Wales or of an equivalent body in Scotland or Northern Ireland.

(3) Persons of the description set out in Schedule 5 are, subject to regulation 26 (cessation of disqualification), disqualified for appointment as a chair, CCG member or social services authority member.

Cessation of disqualification

26.—(1) Where a person is disqualified under paragraph 5 of Schedule 5—

- (a) that person may, after the second anniversary of the day on which they were dismissed, apply in writing to the Board to remove the disqualification for appointment as a chair, CCG member or social services authority member; and
- (b) the Board may decide that the disqualification is removed.

(2) Where the Board refuses an application to remove a disqualification, no further application may be made by that person to the Board until the second anniversary of the day of the refusal and this paragraph applies to any subsequent application.

(3) Where a person is disqualified under paragraph 6 of Schedule 5, the disqualification is to cease on the second anniversary of the termination of the person's appointment, or at the end of such longer period as may have been specified on termination.

Termination of appointment

27.—(1) A chair, CCG member or social services authority member may resign at any time during their term of appointment by giving notice in writing to the Chief Executive of the Board.

(2) Subject to paragraph (3), where the Board is of the opinion that it is not in the interests of the health service that a chair, CCG member or social services authority member should continue to hold office, it may terminate that person's appointment with immediate effect by giving notice to that person in writing to that effect.

(3) The term of appointment of a CCG member or social services authority member must not be terminated under paragraph (2) unless the body responsible for nominating that member has been consulted.

(4) Where a person has been appointed by the Board to be a chair, CCG member or social services authority member, if it comes to the attention of the Board that—

- (a) that person has become disqualified for appointment under regulation 25, the Board must notify that person in writing of such disqualification; or
- (b) at the time of that person's appointment they were so disqualified, the Board must declare that the person in question was not duly appointed and notify that person in writing to that effect.

(5) Upon receipt of any notification referred to in paragraph (4), the person's term of appointment, if any, terminates with immediate effect and that person must cease to act as a chair, CCG member or social services authority member.

Persons who enter relevant premises or who develop a need for nursing care

28.—(1) Subject to paragraphs (2) and (3), where it appears to a relevant body in respect of a person for whom it has responsibility that that person—

- (a) is resident in relevant premises or may need to become resident in such premises; and
- (b) may be in need of nursing care,

that body must carry out an assessment of the need for nursing care.

(2) Before carrying out an assessment under paragraph (1), the relevant body must consider whether its duty under regulation 21(2) is engaged, and if so, it must comply with the requirements of regulation 21 prior to carrying out any assessment under this regulation.

(3) Paragraph (1) does not apply if a relevant body has made arrangements for providing the person with NHS Continuing Healthcare.

(4) Where—

- (a) the relevant body has carried out an assessment pursuant to regulation 21(2); but
- (b) paragraph (3) does not apply because a decision has been made that the person is not eligible for NHS Continuing Healthcare,

that body must nevertheless use that assessment, wherever reasonably practicable, in making its assessment under paragraph (1).

(5) Where—

- (a) the relevant body determines that a person has a need for nursing care pursuant to this regulation; and
- (b) the person has agreed with that body that that person does want to be provided with such nursing care,

paragraph (6) applies.

(6) The relevant body must pay to a registered person for the relevant premises the flat rate in respect of that person's nursing care unless or until that person—

- (a) has their need for nursing care assessed and it is determined that that person no longer has any need for nursing care;
- (b) is no longer resident in the relevant premises;
- (c) becomes eligible for NHS Continuing Healthcare pursuant to this Part; or
- (d) dies.

Persons in receipt of flat rate payments immediately before the relevant date

29.—(1) Where, immediately before the relevant date, a Primary Care Trust was making a flat rate payment in respect of any person pursuant to the National Health Service (Nursing Care in Residential Accommodation) (England) Directions 2007(a), paragraph (2) applies.

(2) The relevant body which has responsibility for a person falling within paragraph (1) must continue to pay to a registered person for the relevant premises the flat rate payment in respect of the person falling within paragraph (1) on and after the relevant date unless or until that person—

- (a) has their need for nursing care assessed on or after the relevant date and it is determined that that person no longer has any need for nursing care;
- (b) is no longer resident in the relevant premises;
- (c) becomes eligible for NHS Continuing Healthcare pursuant to this Part; or
- (d) dies.

Persons in receipt of high band payments immediately before the relevant date

30.—(1) Where, immediately before the relevant date, a Primary Care Trust was making a high band payment in respect of any person pursuant to direction 4 of the National Health Service (Nursing Care in Residential Accommodation) (England) Directions 2007, paragraphs (2) and (3) apply.

(2) The relevant body which has responsibility for a person falling within paragraph (1) must continue to pay the high band payment to a registered person for the relevant premises in respect of the person falling within paragraph (1) on and after the relevant date unless or until that person—

- (a) has their need for nursing care assessed on or after the relevant date and it is determined that that person no longer has any need for nursing care;
- (b) is no longer resident in the relevant premises;
- (c) becomes eligible for NHS Continuing Healthcare pursuant to this Part; or
- (d) dies,

unless paragraph (3) applies.

(3) Where a person in respect of whom a high band payment is being made pursuant to this regulation—

- (a) has their need for nursing care assessed on or after the relevant date; and
- (b) following that assessment it is determined that that person's need for nursing care has diminished to the extent that if the old Guidance were applied, that person would be eligible only for a medium band payment or low band payment,

the relevant body with responsibility for that person must comply with paragraph (4).

(4) Where paragraph (3) applies, the relevant body must give—

- (a) the person in respect of whom the high band payment was being made (and where appropriate that person's representative); and
- (b) the registered person,

written notice of the outcome of the assessment referred to in paragraph (3) and must, no sooner than 14 days beginning with the date that notice is given, thereafter pay the flat rate payment in respect of that person unless or until paragraph (2)(a), (b), (c) or (d) applies.

(a) The Directions can be found at www.dh.gov.uk/en/Publicationsandstatistics/Legislation/DH_078061.

Urgent need

31. Nothing in regulations 28 to 30 prevents a relevant body from temporarily providing nursing care to a person without carrying out an assessment if, in the opinion of that body, the condition of that person is such that those services are required urgently.

Revocation and transitional provisions

32.—(1) Where a Primary Care Trust has, before the relevant date, determined that a person is eligible for NHS Continuing Healthcare under direction 2 of the NHS Continuing Healthcare (Responsibilities) Directions 2009(a) (“the Responsibilities Directions”) or the Delayed Discharges (Continuing Care) Directions 2009(b) (“the Delayed Discharges Directions”), the relevant body with responsibility for that person on the relevant date must continue to provide NHS Continuing Healthcare unless—

- (a) regulation 21(2)(b) applies;
- (b) an assessment of eligibility for NHS Continuing Healthcare is undertaken pursuant to regulation 21; and
- (c) that body determines that the person is no longer eligible for NHS Continuing Healthcare.

(2) Where a Primary Care Trust has, before the relevant date—

- (a) started an initial screening process to decide whether to undertake an assessment of a person’s eligibility for NHS Continuing Healthcare under direction 2(4) of the Responsibilities Directions or the Delayed Discharges Directions but not completed the process, the relevant body with responsibility for that person must—
 - (i) complete the initial screening process as if it had commenced under regulation 21(4), and
 - (ii) where the outcome of that process is that an assessment for NHS Continuing Healthcare is required, assess that person’s eligibility for NHS Continuing Healthcare under this Part; or
- (b) started to assess a person’s eligibility for NHS Continuing Healthcare under paragraphs (5) to (7) of direction 2 of the Responsibilities Directions or the Delayed Discharges Directions, the relevant body with responsibility for that person must complete the assessment as if it had commenced under regulation 21.

(3) This paragraph applies where—

- (a) a Strategic Health Authority has before the relevant date, received an application for a review of procedure or a decision pursuant to direction 4(2) of the Responsibilities Directions in respect of which a decision has not been made before the relevant date; or
- (b) on or after the relevant date the Board receives an application for a review of procedure or a decision which would have been a valid application under direction 4(2) of the Responsibilities Directions if made before the relevant date.

(4) Where paragraph (3) applies, the Board must organise or complete the review in accordance with regulation 23 (the Board’s duty: reviewing decisions).

(5) Subject to regulation 27, the appointment of a person appointed as a chair in accordance with the Responsibilities Directions continues for such period as it would have continued if those directions had not been revoked, and such a person must be treated as if they had been appointed by the Board under regulation 23.

(6) Subject to regulation 27, the appointment of a person appointed as a PCT member or social services authority member in accordance with the 2009 Directions continues for such period as it would have continued if those directions had not been revoked and—

(a) The Directions can be found at www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_106176.

(b) The Directions can be found at www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_106178.

- (a) such a person must be treated as if they had been appointed by the Board under regulation 24; and
 - (b) in the case of a PCT member, as if that person were appointed as a CCG member in respect of each CCG whose area falls wholly or partly within the area of the PCT in relation to which they were a PCT member.
- (7) The following directions are revoked—
- (a) the National Health Service (Nursing Care in Residential Accommodation) (England) Directions 2007(a) which came into force on 1st October 2007;
 - (b) the National Health Service (Nursing Care in Residential Accommodation) (Amendment) (England) Directions 2009 which came into force on 1st October 2009(b);
 - (c) the NHS Continuing Healthcare (Responsibilities) Directions 2009(c) which came into force on 1st October 2009; and
 - (d) the Delayed Discharges (Continuing Care) Directions 2009 which came into force on 28th September 2009(d).

PART 7

Standing rules: decisions about drugs and other treatments

Interpretation

33. In this Part—

“health care intervention” includes the use of a medicine or medical device, diagnostic technique, surgical procedure or other therapeutic intervention;

“NICE” means—

- (a) until the coming into force of section 232 of the 2012 Act(e), the National Institute for Health and Clinical Excellence(f); and
- (b) from the coming into force of that section, the National Institute for Health and Care Excellence;

“relevant NICE recommendations” means—

- (a) any directions given by the Secretary of State as to the application of sums paid to a Primary Care Trust under section 228 of the 2006 Act (public funding by Primary Care Trusts) in relation to a health care intervention recommended by NICE; and
- (b) from the coming into force of section 237(8) of the 2012 Act (NICE advice, guidance, information and recommendations), recommendations specified, or recommendations of a description specified, in regulations made under that section where the relevant body—
 - (i) is specified in such regulations as required to comply with the recommendation, or
 - (ii) is a health and social care body of a description specified in such regulations as a health and social care body that is required to comply with the recommendation.

(a) The Directions can be found at www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_078061.

(b) The Directions can be found at www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_106179.

(c) The Directions can be found at www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_106176.

(d) The Directions can be found at www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_106178.

(e) Section 232 of the 2012 Act establishes a body corporate to be known as the National Institute for Health and Care Excellence.

(f) The National Institute for Health and Clinical Excellence is a Special Health Authority established by S.I. 1999/220, as amended by S.I. 1999/2219, 2002/1760, 2005/497 and 2012/476. It is abolished by section 248 of the 2012 Act.

Duty of a relevant body in respect of the funding and commissioning of drugs and other treatments

34.—(1) A relevant body must have in place arrangements for making decisions and adopting policies on whether a particular health care intervention is to be made available for persons for whom the relevant body has responsibility.

(2) Arrangements under paragraph (1) must—

- (a) ensure that the relevant body complies with relevant NICE recommendations; and
- (b) include arrangements for the determination of any request for the funding of a health care intervention for a person, where there is no relevant NICE recommendation and the relevant body's general policy is not to fund that intervention.

Duty to give reasons for decisions

35.—(1) A relevant body must—

- (a) publish on its website a written statement of its reasons for any general policy it has on whether a particular healthcare intervention is to be made available for persons for whom it has responsibility; or
- (b) where it has not published such a statement, provide a written statement of the reasons for any such policy when any person makes a written request for such a statement.

(2) Where a relevant body—

- (a) makes a decision to refuse a request for the funding of a health care intervention for a person; and
- (b) its general policy is not to fund that intervention,

the relevant body must provide that person with the reasons for that decision in writing.

Duty to provide written information

36. Each relevant body must compile information in writing describing the arrangements it has made pursuant to the requirements in regulation 34 and must ensure that that information is—

- (a) published on the website of the relevant body; and
- (b) available to inspect at the head or main office of the relevant body.

Transitional provisions

37.—(1) For the purposes of this regulation, a relevant body has responsibility for a person in respect of a healthcare intervention only if it has responsibility for that person in relation to services which involve, or would if the intervention was funded involve, the provision of that intervention.

(2) Where, before the relevant date—

- (a) a person has made a request for a written statement of the reasons for a Primary Care Trust's general policy on whether a particular health care intervention is to be funded pursuant to direction 3(1) of the Directions to Primary Care Trusts and NHS trusts concerning decisions about drugs and other treatments 2009 which came into force on 1st April 2009 (“the Decisions Directions”)(a); and
- (b) a written statement of reasons has not been provided by the Primary Care Trust to whom that request was made before the relevant date in accordance with that direction,

the relevant body with responsibility for that person must provide a written statement of reasons as soon as reasonably practicable as if the request had been made under regulation 35(1)(b).

(a) The Directions can be found at www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_096067.

- (3) Where, before the relevant date, a Primary Care Trust—
- (a) has made a decision to refuse a request for the funding of a health care intervention in respect of a person where the Primary Care Trust’s general policy is not to fund that intervention; but
 - (b) has not provided that person with a written statement of reasons for that decision pursuant to direction 3(3) of the Decisions Directions,

the relevant body with responsibility for that person must provide a written statement of reasons to that person as soon as reasonably practicable as if regulation 35(2) applied.

- (4) Where, before the relevant date, a Primary Care Trust—
- (a) has made a decision to fund a health care intervention for a person where the Primary Care Trust’s general policy is not to fund that intervention; but
 - (b) has not notified that person of that decision,

the relevant body with responsibility for that person must notify that person as soon as reasonably practicable of that decision, and fund that intervention.

(5) Where, before the relevant date, a Primary Care Trust has received a request for the funding of a health care intervention but has not yet determined it pursuant to arrangements made under direction 2(3)(a) of the Decisions Directions, the relevant body with responsibility for the person who made the request must—

- (a) decide whether or not to fund that intervention; and
- (b) if the decision is to refuse to fund that intervention, provide a written statement of reasons to that person as soon as reasonably practicable as if regulation 35(2) applied.

PART 8

Standing rules: choice of health service provider

Interpretation

38. In this Part—

“elective referral” means referral by a general medical practitioner, general dental practitioner or optometrist to a health service provider for treatment that is not identified as being immediately required at the time of referral;

“Choice Directions” means the Primary Care Trusts (Choice of Secondary Care Provider) Directions 2009 which came into force on 1st April 2009(a);

“prison” includes any other institution to which prison rules made under section 47 of the Prison Act 1952(b) apply.

Duty to ensure persons are offered a choice of health service provider

39.—(1) A relevant body must make arrangements to ensure that a person—

- (a) who requires an elective referral; and
- (b) for whom that body has responsibility,

is given the choices specified in paragraph (2).

(a) The Directions can be found at www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_093004. These Directions were amended by further Directions that came into force on 1st April 2012 which can be found at the same link.

(b) 1952 c.47.

(2) Subject to regulations 40 and 41, the choices specified for the purposes of this paragraph are the choice, in respect of a first outpatient appointment with a consultant or a member of a consultant's team, of—

- (a) any clinically appropriate health service provider with whom any relevant body has a commissioning contract for the service required as a result of the referral; and
- (b) any clinically appropriate team led by a named consultant who is employed or engaged by that health service provider.

(3) A relevant body must make arrangements to ensure that a person—

- (a) who requires an elective referral for mental health services; and
- (b) for whom that body has responsibility in relation to the services in respect of which the referral is made,

is given the choice specified in paragraph (4).

(4) Subject to regulation 41, the choice specified for the purposes of this paragraph is the choice, in respect of a first outpatient appointment with a health care professional or a member of a health care professional's team, of any clinically appropriate team led by a named health care professional who is employed or engaged by the health service provider to whom the patient has been referred.

(5) The arrangements referred to in paragraphs (1) and (3) must include such arrangements as are necessary to ensure that a person may make the choices specified in those paragraphs where that person—

- (a) has not been offered that choice by the person making the initial referral; and
- (b) notifies the relevant body who has responsibility for that person that that choice was not offered.

(6) For the purposes of this Part, a health service provider, or a team led by a consultant or a health care professional, is clinically appropriate if, in the opinion of the person making the referral, they offer services that are clinically appropriate for that person in respect of the condition for which that person is referred.

Services to which the duties as to choice do not apply

40.—(1) Regulation 39(1) does not apply to the following services—

- (a) cancer services which are subject to the 2 week maximum waiting time by virtue of regulation 52;
- (b) maternity services; or
- (c) mental health services.

(2) Regulation 39(1) and (3) do not apply to any service where it is necessary to provide urgent care.

Persons to whom the duties as to choice do not apply

41. Regulations 39(1) and (3) do not apply in relation to any person who is—

- (a) detained under the 1983 Act;
- (b) detained in or on temporary release from prison; or
- (c) serving as a member of the armed forces.

Duty to publicise and promote information about choice

42.—(1) A relevant body must make arrangements to ensure that the availability of choice under the arrangements it makes pursuant to regulation 39 are publicised and promoted.

(2) Without prejudice to the generality of paragraph (1), those arrangements must include arrangements for—

- (a) publicising, and promoting awareness of, information about—
 - (i) health service providers for the purpose of enabling a person to choose a health service provider in accordance with arrangements that the relevant body has made pursuant to regulation 39(1),
 - (ii) consultant-led teams for the purpose of enabling a person to choose a clinically appropriate team in accordance with arrangements that the relevant body has made pursuant to regulation 39(1), and
 - (iii) teams led by health care professionals providing mental health services for the purpose of enabling a person to choose a clinically appropriate team in accordance with arrangements that the relevant body has made pursuant to regulation 39(3); and
- (b) publicising details, and promoting awareness, of where that information may be found.

Transitional provision

43.—(1) Where, before the relevant date—

- (a) a person requires an elective referral;
- (b) that person has not yet seen a clinically appropriate secondary care provider as a result of the referral; and
- (c) that person had not been offered the choice of any clinically appropriate secondary care provider in relation to that referral,

the relevant body that has responsibility for that person on and after the relevant date must comply with paragraph (2).

(2) The relevant body must ensure that, in respect of a person falling within paragraph (1), it complies with directions 2 to 4 of the Choice Directions in respect of the person as if—

- (a) the Choice Directions continued in force on and after the relevant date in respect of that person;
- (b) references to “Primary Care Trust” in those directions, and any relevant guidance referred to in those directions, were a reference to the relevant body that has responsibility for that person; and
- (c) references to “secondary care provider” were references to “health service provider” within the meaning of these Regulations.

(3) Where—

- (a) a person—
 - (i) makes a complaint to a Primary Care Trust before the relevant date in accordance with a complaints procedure published pursuant to direction 7 of the Choice Directions, and
 - (ii) that complaint has not been resolved in accordance with that published procedure before the relevant date; or
- (b) a person makes a complaint to a relevant body on or after the relevant date in respect of failure before that date to ensure that choice is offered pursuant to direction 2 of the Choice Directions, or failure to publicise or promote such choice in accordance with direction 6 of those Directions,

the relevant body that has responsibility for that person on and after the relevant date must comply with paragraph (4).

(4) The relevant body must ensure that, in respect of a person who makes a complaint falling within paragraph (3)(a) or (b), it deals with the complaint in accordance with the procedures published pursuant to direction 7 of the Choice Directions by the Primary Care Trust that previously had responsibility for that person.

(5) In this regulation, “clinically appropriate secondary care provider” has the meaning given in direction 1(2) and (3)(a) of the Choice Directions.

PART 9

Standing rules: waiting times

Interpretation

44.—(1) In this Part—

“appropriate treatment” means treatment that is the first treatment provided to a person as a result of, and in response to, an elective referral;

“eligible referrer” means—

- (a) a general dental practitioner,
- (b) a general medical practitioner,
- (c) a person approved to make an elective referral under arrangements made by the relevant body which has responsibility for the person being referred, and
- (d) any other person whose request to refer is accepted by—
 - (i) a consultant,
 - (ii) a member of a consultant’s team, or
 - (iii) persons providing interface services where a person who has been referred may be referred on from those services to a consultant or consultant-led team,

who is to provide the assessment or treatment required as a result of a referral;

“elective referral” means referral by an eligible referrer to a health service provider for assessment or treatment that is not identified as being immediately required at the time of referral;

“each data collection period” means each calendar month and the end of such a period means the end of the last day of the calendar month in question;

“interface services” means services that are provided otherwise than by a consultant-led team, which provide clinical triage, assessment and treatment services, but does not include mental health services or services provided under a primary care contract;

“registered healthcare professional” means a person who is a member of a profession regulated by one of the following bodies—

- (a) the General Medical Council,
- (b) the Nursing and Midwifery Council, or
- (c) the Health and Care Professions Council;

“specialist” means a registered healthcare professional working as a consultant, or as part of a consultant-led team, who specialises in the area of professional practice which is most appropriate for the diagnosis and treatment of the type of suspected cancer in question;

“start date” means the date on which the person’s referral request was received by the health service provider to whom that person has been referred for the provision of health care services by—

- (a) in regulations 45 to 51—
 - (i) an eligible referrer; or
 - (ii) themselves, with the prior approval of an eligible referrer, or
- (b) in regulations 52 and 53, a general medical practitioner, a general dental practitioner or a person authorised to act on their behalf;

“suitable health service provider”, in relation to a person who has been referred for assessment or treatment, is a health service provider who—

- (a) can provide services which consist of, or include, treatment which is clinically appropriate for that person in response to the reasons for the referral, and
- (b) will provide those services pursuant to a commissioning contract with a relevant body;

“treatment” means an intervention that is intended to manage a person’s disease, condition or injury and, insofar as reasonably practicable, avoid further interventions, but does not include a therapy or healthcare intervention referred to in regulation 46(3);

“treatment for suspected cancer” means—

- (a) assessment by a specialist in order to progress towards a diagnosis, or
- (b) treatment for suspected cancer that is provided by a specialist;

“Waiting Times Directions” means the Primary Care Trusts and Strategic Health Authorities (Waiting Times) Directions 2010 which came into force on 1st April 2010^(a).

(2) For the purposes of this Part, where reference is made to an appointment date being reasonable, it is reasonable if it falls at least 3 weeks after the date on which the offer of the appointment was made.

Duty to meet the maximum waiting times standards

45.—(1) A relevant body must make arrangements to ensure that persons—

- (a) for whom the relevant body has responsibility; and
- (b) who require an elective referral,

commence appropriate treatment in accordance with paragraph (2).

(2) The requirement referred to in paragraph (1) is that at the end of each data collection period, appropriate treatment has commenced within the period of eighteen weeks beginning with the start date in not less than—

- (a) 95% of cases where the appropriate treatment is provided during that data collection period without admitting as an in-patient a person receiving that treatment; and
- (b) 90% of cases where a person is admitted as an in-patient in order to receive that treatment during that data collection period.

(3) A relevant body must make arrangements to ensure that at the end of each data collection period, not less than 92% of the persons falling within paragraph (4) have been waiting to commence treatment for less than 18 weeks.

(4) A person falls within this paragraph if—

- (a) the relevant body has responsibility for that person;
- (b) there has been a start date in respect of that person; and
- (c) the person’s waiting time period, as specified in regulation 46, has not come to an end.

(5) Where—

- (a) a decision has been made to admit a person to hospital for treatment as an in-patient as a result of, and in response to, an elective referral;
- (b) that person has been offered at least two different reasonable appointment dates for admission to hospital for that treatment but has declined to attend on any of the dates offered,

the period of time described in paragraph (6) may be excluded from the calculation of the period of time for which that person has been waiting to commence appropriate treatment for the purpose of calculating the percentage of persons falling under paragraph (2)(b).

(6) The period of time to be excluded for the purposes of the calculation referred to in paragraph (5)—

- (a) begins with the date of the earliest appointment date that was offered; and
- (b) ends on the date on which the person is available again for admission to hospital for the treatment required as a result of, and in response to, the elective referral, where that

(a) The Directions can be found at www.dh.gov.uk/en/publicationsandstatistics/Publications/PublicationsLegislation/DH_113557.

person has notified the health service provider, whether verbally or in writing, of that date.

The waiting time period

46.—(1) The waiting time period for a person, as referred to in regulation 45(4)(c), begins with the start date and ends when any of the following paragraphs applies.

(2) The referred person received appropriate treatment.

(3) The referred person commenced therapy or received a healthcare science intervention where a consultant, a member of a consultant-led team or an individual providing an interface service decides that the therapy or that intervention is the treatment that is most appropriate for that person.

(4) A person's name is added to a national transplant waiting list.

(5) The referred person is notified, verbally or in writing, that the calculation of the period of eighteen weeks beginning on the start date no longer applies in their case because—

(a) it is more appropriate for that person to receive treatment from a primary care service;

(b) a clinical decision is made to start a period of monitoring of that person prior to any decision being made as to what, if any, treatment should be provided;

(c) a clinical decision is made that no treatment should be provided to that person;

(d) they did not attend the first appointment made as a result of the referral by the health service provider to whom they were referred and they—

(i) had been made aware of the consequences of not attending an appointment, and

(ii) had not requested in advance of the date for the first appointment that the appointment be re-arranged for a different date; or

(e) they are being discharged back in to the care of their general medical practitioner because they did not attend an appointment, other than an appointment referred to in subparagraph (d), made as a result of the referral by the health service provider to whom they were referred and they—

(i) had been made aware of the consequences of not attending an appointment, and

(ii) had not requested in advance of the date for that appointment that the appointment be re-arranged for a different date.

Application of duty to offer an alternative provider

47.—(1) Regulation 48 applies if the conditions in paragraph (2) to (6) are met.

(2) A person has been referred to a health service provider (“the relevant health service provider”) for the provision of health care services by—

(a) an eligible referrer; or

(b) themselves, with the prior approval of an eligible referrer.

(3) The referral is for assessment or treatment in the course of the provision of health care services by—

(a) a consultant;

(b) a member of a consultant's team; or

(c) persons providing interface services where a person who has been referred may be referred on from those services to a consultant or consultant-led team.

(4) The relevant health service provider, or the relevant body which has responsibility for the person referred, has been notified that the person referred—

(a) has not commenced appropriate treatment; or

(b) will not have commenced appropriate treatment,

within eighteen weeks, beginning with the start date.

(5) The notification referred to in paragraph (4) was given by—

- (a) in the case of the relevant health service provider or a CCG, the person referred or a person lawfully acting on their behalf; or
- (b) in the case of the Board, a CCG which has been notified by the person referred or a person lawfully acting on their behalf.

(6) The relevant body which has responsibility for the person referred is satisfied that the person has not commenced or will not commence appropriate treatment within eighteen weeks, beginning with the start date.

Duty to offer an alternative provider

48.—(1) Subject to regulation 49, where this regulation applies, the relevant body which has responsibility for the person referred must take all reasonable steps to ensure that that person is offered an appointment in accordance with paragraphs (2) to (4).

(2) The appointment offered must be with a consultant, or a member of a consultant’s team, at a suitable health service provider other than the relevant health service provider.

(3) The appointment must be an appointment to commence treatment earlier than the person referred would have commenced treatment if they had continued to wait for treatment at the relevant health service provider.

(4) If there is more than one suitable health service provider, the person referred must be offered a choice of appointment with more than one suitable health service provider that meets the requirements of paragraphs (2) and (3).

(5) In this regulation and regulation 49, “relevant health service provider” has the meaning given to it in regulation 47(2).

Exceptions to the duty

49.—(1) Regulation 48 does not apply in the circumstances described in any of paragraphs (2) to (10).

(2) The person referred did not attend an appointment made by the relevant health service provider in response to the referral where—

- (a) the date for the appointment was reasonable;
- (b) that person had been made aware of the consequences of not attending appointments; and
- (c) that person had not requested in advance that the date for that appointment be re-arranged.

(3) The person referred did not attend a re-arranged appointment made by the relevant health service provider in response to the referral where—

- (a) that person had re-arranged the date of the appointment;
- (b) the original date for the appointment had been reasonable; and
- (c) that person had been made aware of the consequences of not attending appointments.

(4) The patient chose to commence treatment on a date falling after the end of the period of 18 weeks beginning with the start date where—

- (a) that patient had been offered a reasonable appointment date falling within that period; or
- (b) they decided that they did not want to be offered any appointment dates within that period.

(5) The person referred decided that they did not want to commence treatment.

(6) The person referred was unable to commence treatment during the period of 18 weeks beginning with the start date for reasons not related to the relevant health service provider, or relevant body which has responsibility for that person, where that person—

- (a) has been offered a reasonable appointment date falling within that period; or
 - (b) was unable to make themselves available for any appointment dates within that period.
- (7) A person falling within regulation 47(3)(a), (b) or (c) has assessed the person referred and decided—
- (a) that it is in the best clinical interests of that patient to commence treatment after the end of the period of 18 weeks beginning with the start date;
 - (b) that the person does not need treatment; or
 - (c) to refer the patient back to primary care services prior to any treatment commencing.
- (8) A person falling within regulation 47(3)(a), (b) or (c) has assessed the person referred and decided that the person requires a period of monitoring which consist of or includes being re-assessed at intervals within the period of 18 weeks beginning with the start date.
- (9) The patient is placed on the national transplant waiting list.
- (10) The patient is referred for the purpose of receiving maternity services.

Duty to have regard to guidance

50. In carrying out its duties under regulations 45 and 48, a relevant body must have regard to the document entitled “The Referral to Treatment Consultant-led Waiting Times Rules Suite” dated January 2012(a).

Duty to notify

51. Where—

- (a) a person meets the conditions in regulation 47(2) and (3);
- (b) the Board has responsibility for that person in respect of the health care service to be provided on referral; and
- (c) a CCG receives notification from that person, or a person acting lawfully on that person’s behalf, that they—
 - (i) have not commenced appropriate treatment; or
 - (ii) will not commence appropriate treatment, within 18 weeks beginning with the start date,

that CCG must notify the Board in writing of that information.

Duty to make arrangements to provide an appointment with a specialist for those patients urgently referred for treatment for suspected cancer

52.—(1) A relevant body must make arrangements to ensure that persons—

- (a) for whom the relevant body has responsibility; and
- (b) in respect of whom an urgent referral for suspected cancer is made by—
 - (i) a general medical practitioner or a person authorised to act on their behalf, or
 - (ii) a general dental practitioner or a person authorised to act on their behalf,

are provided with treatment for suspected cancer in accordance with paragraph (2).

(2) The requirement referred to in paragraph (1) is that at the end of each data collection period, treatment for suspected cancer has commenced within the period of 2 weeks beginning with the start date in not less than 93% of cases where that treatment is provided in that data collection period.

(3) Where—

(a) The Rules Suite can be found at transparency.dh.gov.uk/2012/06/29/rtt-waiting-times-guidance/.

- (a) the person referred did not attend an appointment made by a health service provider in response to the urgent referral; and
- (b) that person had not requested in advance of the appointment that the date for that appointment be rearranged,

the period of time described in paragraph (4) is to be excluded from the calculation of the period of 2 weeks beginning with the start date referred to in paragraph (2).

(4) The period of time to be excluded for the purposes of paragraph (3)—

- (a) begins with the start date; and
- (b) ends on the date on which the health service provider receives notification from the person who has been urgently referred that they are available again for an appointment for treatment for suspected cancer.

(5) In carrying out its duties under this regulation, a relevant body must have regard to the National Institute for Health and Clinical Excellence Referral Guidelines for Suspected Cancer dated June 2005^(a).

Duty to offer alternative provider for treatment for suspected cancer

53.—(1) Paragraph (2) applies where—

- (a) a person has been referred urgently for treatment for suspected cancer to a health service provider (“the relevant provider”);
- (b) the referral is made by—
 - (i) a general medical practitioner or a person authorised to act on their behalf, or
 - (ii) a general dental practitioner or a person authorised to act on their behalf;
- (c) the referral is for an appointment with a specialist with a view to diagnosis or treatment of cancer;
- (d) the referred person, or a person lawfully acting on their behalf, notifies the relevant provider or the relevant body which has responsibility for the person referred, that they have not had an appointment, or will not have an appointment, within two weeks beginning with the date on which the person’s referral request is received by the relevant provider (“the relevant period”); and
- (e) the relevant provider or the relevant body is satisfied that the person referred has not or will not have an appointment within the relevant period.

(2) Where this paragraph applies, the relevant body which has responsibility for the person referred must take all reasonable steps to ensure that the person is offered an appointment in accordance with paragraphs (3) to (5).

(3) The appointment must be with a specialist at a suitable health service provider other than the relevant provider.

(4) The appointment must be at an earlier date than the appointment the person would have had if they had continued to wait for an appointment at the relevant provider.

(5) If there is more than one suitable health service provider the patient must be offered an appointment falling within paragraphs (2) and (3) at more than one such provider.

(6) Paragraph (2) does not apply if the person—

- (a) was made aware of the consequences of not attending appointments and did not attend an appointment made by the relevant provider in response to the referral; or
- (b) chose not to attend an appointment within the relevant period.

^(a) The Guidelines can be found at www.nice.org.uk/CG027.

Advice and assistance

54.—(1) Each CCG must—

- (a) establish a service for the purpose of providing advice and assistance to persons—
 - (i) for whom it has responsibility, and
 - (ii) who meet the conditions set out in regulation 47(2) and (3) or 53(1)(a) to (c) (“relevant persons”);
- (b) publish the name and contact details of the service; and
- (c) take reasonable steps to communicate the name and contact details of that service to any relevant persons for which it has responsibility.

(2) Each CCG must make arrangements to ensure that any health service provider providing services to a relevant person pursuant to a commissioning contract with that CCG—

- (a) establishes a service for the purpose of providing advice and assistance to relevant persons referred to the provider;
- (b) publishes the name and contact details of that service; and
- (c) takes reasonable steps to communicate the name and contact details of that service to any relevant persons referred to the provider for whom the relevant body is responsible.

Transitional provision

55.—(1) Where, before the relevant date—

- (a) a Primary Care Trust or Strategic Health Authority is responsible for a person pursuant to direction 1(4) or (5) of the Waiting Times Directions;
- (b) that person falls within direction 3(2) and (3) of the Waiting Times Directions, having been referred before the relevant date,

the relevant body that has responsibility for that person on and after the relevant date must comply with paragraph (2).

(2) The relevant body must ensure that, in respect of a person specified in paragraph (1), it complies with directions 3 to 6 of the Waiting Times Directions in respect of the person as if—

- (a) the Waiting Times Directions continued in force on and after the relevant date;
- (b) references to “Primary Care Trust” or “Strategic Health Authority” in those directions, and any relevant guidance referred to in those directions, were a reference to the relevant body that has responsibility for that person on and after the relevant date; and
- (c) the relevant body had had responsibility for that person from the date on which that person was referred for the purpose of calculating any periods of time referred to in those directions or that guidance.

(3) Where, before the relevant date—

- (a) a Primary Care Trust or Strategic Health Authority is responsible for a person pursuant to direction 1(4) or (5) of the Waiting Times Directions; and
- (b) that person falls within direction 9(1)(a), (b) and (c) of the Waiting Times Directions, having been referred before the relevant date,

the relevant body that has responsibility for that person on and after the relevant date must comply with paragraph (4).

(4) The relevant body must ensure that, in respect of a person specified in paragraph (3), it complies with directions 9 and 10 of the Waiting Times Directions in respect of the person as if—

- (a) the Waiting Times Directions continued in force on and after the relevant date;
- (b) references to “Primary Care Trust” or “Strategic Health Authority” in those directions, and any relevant guidance referred to in those directions, were a reference to the relevant body that has responsibility for that person on and after the relevant date; and

- (c) the relevant body had had responsibility for that person from the date on which that person was referred for the purpose of calculating any periods of time referred to in those directions or that guidance.

PART 10

Standing rules: funding of therapies for Multiple Sclerosis

Scheme for the funding of certain disease modifying therapies for Multiples Sclerosis

56.—(1) A relevant body must, in exercising its functions under or by virtue of section 3(1), 3A(1) or 3B of the 2006 Act, ensure that—

- (a) a scheme product is supplied or administered in accordance with the scheme to a scheme patient,
- (b) a scheme product continues to be supplied or administered in accordance with the scheme to a scheme patient where such a patient was receiving such a course of treatment immediately before the relevant date unless the patient’s consultant has determined, in consultation with the scheme patient, that the scheme product is no longer clinically appropriate;
- (c) a scheme product is supplied or administered to a patient with multiple sclerosis for the purpose of that person’s treatment for that condition where that patient—
 - (i) is not a scheme patient, but
 - (ii) was, on 4th February 2002, and is, immediately before the relevant date, receiving such a course of treatment for that condition.

(2) In this Part—

“scheme” means the arrangement between the Department of Health (England), the National Assembly for Wales, the Scottish Ministers, the Northern Ireland Department of Health, Social Security and Public Safety, Biogen Idec Inc., Bayer PLC, Merck Serono Limited, and Teva Pharmaceutical Industries Limited together with Aventis Pharma Limited, dated 1st February 2002, for the supply and administration of products for the treatment of multiple sclerosis^(a);

“scheme patient” means a patient with multiple sclerosis who is eligible to receive treatment under the scheme and who consents to receive such treatment;

“scheme product” means—

- (a) Interferon beta-1a: Avonex and Rebif (22mg and 44mg);
- (b) Interferon beta – 1b: Betaferon; or
- (c) Glatiramer acetate: Copaxone,

which is given for the treatment of multiple sclerosis and which is manufactured by a company that is a party to the scheme.

(a) The arrangement can be found at www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthservicecirculars/DH_4004332 – see Annex A.

PART 11

Financial duties of a relevant body in relation to administration

Matters relating to administration in revenue resource use by a relevant body

57.—(1) Subject to paragraph (3), for the purposes of section 223E(3) and section 223J(3) of the Act (powers to direct that revenue resource use by a relevant body in a financial year attributable to prescribed administrative matters does not exceed specified amounts), the following matters relating to administration are prescribed—

- (a) the payment of remuneration, national insurance, pensions, allowances or gratuities to the persons listed in paragraph (2), insofar as the payment is attributable to any of the activities referred to in paragraph (1)(d) or (e);
- (b) the provision of education and training for the persons listed in paragraph (2), where the education or training relates to any of the activities referred to in paragraph (1)(d) or (e);
- (c) securing the provision of goods, facilities or services for use by a relevant body in the exercise of its functions^(a), including costs relating to—
 - (i) accommodation, including the cost of rent, rates, utilities and maintenance;
 - (ii) information technology, including telecommunications and computer maintenance;
 - (iii) office services, including stationery, postage and rental of office equipment;
 - (iv) management consultancy;
 - (v) services to support arranging the provision of the services referred to in paragraph (3); and
 - (vi) depreciation, amortisation, impairment, write-off or other alterations in the value of assets;
- (d) the costs incurred in the exercise of—
 - (i) the Board's functions in relation to CCGs, or
 - (ii) a relevant body's functions of arranging for the provision of the services referred to in paragraph (3),including costs which are incurred in the carrying out of activities designed to improve the exercise of those functions, but excluding costs incurred in relation to activities whose sole or primary purpose is to improve the quality of those services;
- (e) the costs, other than those referred to in paragraph (1)(a) to (d), which are incurred in the carrying out of the following administrative or support activities—
 - (i) human resources,
 - (ii) finance,
 - (iii) corporate, business and administrative support;
 - (iv) management,
 - (v) governance,
 - (vi) formulation and monitoring of policy and strategy in relation to the exercise of functions,
 - (vii) administration of grant payments,
 - (viii) legal and regulatory advice,
 - (ix) marketing and communications, and
 - (x) programme and project management.

(a) Section 1H of the 2006 Act sets out the general functions of the Board and section 11 of the 2006 Act sets out the general functions of CCGs.

- (2) The persons referred to in paragraph (1)(a) and (b) are—
- (a) employees of a relevant body;
 - (b) non-executive members of the Board;
 - (c) members of a CCG governing body;
 - (d) members of committees of the Board, a CCG or a CCG governing body and members of sub-committees of those committees;
 - (e) members of a CCG who are individuals; and
 - (f) individuals authorised to act on behalf of a member of a CCG in dealings between the member and the CCG.
- (3) The prescribed matters relating to administration do not include—
- (a) payments made to persons providing services as part of the health service under arrangements made by a relevant body, in respect of the provision of such services pursuant to those arrangements; and
 - (b) payments made by a relevant body under or by virtue of section 12A of the 2006 Act.

Signed by authority of the Secretary of State for Health.

Earl Howe
Parliamentary Under-Secretary of State,
Department of Health

3rd December 2012

SCHEDULE 1

Regulation 4

Additional persons for whom a CCG has responsibility

1. In this Schedule—

“care home” and “children’s home” have the same meaning as in the Care Standards Act 2000(a);

“child” means a person under the age of 18;

“continuing care” means care provided over an extended period of time to a person to meet physical or mental health needs which have arisen as the result of illness;

“independent hospital” means a hospital as defined in section 275(1) of the 2006 Act (interpretation), that is not a health service hospital as defined there;

“local authority” means a county council, a district council for an area for which there is no county council, a London borough council, the Common Council of the City of London, or the Council of the Isles of Scilly;

“planned service” means any service whose provision is planned and arranged by a CCG as part of the health service in response to the results of an assessment of a person’s physical or mental health needs and which is intended to bring about or promote a specific outcome in relation to those needs.

2. The list of persons referred to in regulation 4(1) is as follows—

- (a) every person present in the CCG’s area, in relation to the provision of ambulance services or accident and emergency services, whether provided at a hospital accident and emergency department, a minor injuries unit, a walk-in centre or elsewhere (but excluding any services provided after the person has been accepted as an in-patient, or at an out-patient appointment);

(a) 2000 c. 14.

- (b) every person aged 18 or over who falls within paragraph 3, in relation to the provision of the accommodation or services referred to in paragraph 3(b);
- (c) every child who falls within paragraph 4;
- (d) every person who falls within paragraph 5 in relation to the provision of the accommodation or services referred to in paragraph 5(b);
- (e) every person who falls within paragraph 6 in relation to the provision of the accommodation or services referred to in paragraph 6(b);
- (f) every child who falls within paragraph 7 in relation to the provision of the accommodation or services referred to in paragraph 7(b);
- (g) every child who falls within paragraph 8;
- (h) every person present in the CCG's area who is resident outside the United Kingdom and not provided with primary medical services by a member of any CCG;
- (i) every person resident in Scotland, Wales or Northern Ireland and present in the CCG's area who is a qualifying patient within the meaning of section 130C of the 1983 Act^(a)(section 130A:supplemental), and not provided with primary medical services by a member of any CCG;
- (j) every person who is a qualifying patient within the meaning of section 130C of the 1983 Act and liable to be detained under that Act in a hospital or registered establishment (within the meaning of that Act) in the CCG's area.

3. A person falls within this paragraph if—

- (a) the CCG has made an arrangement in the exercise of its commissioning functions (by itself or jointly with a local authority) by virtue of which the person is to be provided with services to meet his or her continuing care needs,
- (b) those services consist of or include the provision of the following accommodation and services to meet the person's continuing care needs—
 - (i) accommodation in a care home or independent hospital situated in the area of another CCG, and
 - (ii) at least one planned service (other than a service consisting only of NHS-funded nursing care) which is connected to the provision of such accommodation (whether or not the accommodation is arranged by the CCG referred to in sub-paragraph (a)),
- (c) the person is resident in that accommodation and continues to need that planned service (or those planned services), and
- (d) the person would not be a person for whom the CCG is responsible under section 3(1A)(a) of the 2006 Act.

4.—(1) A child falls within this paragraph if both of sub-paragraphs (2) and (3) apply to the child.

(2) This sub-paragraph applies to a child if any of the following is the case—

- (a) the child is looked after by a local authority within the meaning of section 22 of the Children Act 1989^(b) (general duty of local authority in relation to children looked after by them), other than by way of being accommodated in a secure children's home in respect of which the National Health Service Commissioning Board^(c) must arrange for the provision of services to children detained there^(d);

(a) Section 130C was inserted by section 30 of the Mental Health Act 2007 (c. 12). It has been amended, in relation to Wales, by Schedule 1 to the Mental Health (Wales) Measure 2010 (nawm 7).

(b) 1989 c. 41.

(c) The National Health Service Commissioning Board is established by section 1H of the 2006 Act as inserted by section 9(1) of the 2012 Act.

(d) See regulation 10 of these Regulations (services to be provided by the Board for prisoners and other detainees).

- (b) the child is a relevant child within the meaning of section 23A of that Act^(a)(the responsible authority and relevant children);
 - (c) the child is a person to whom section 24(1A) or (1B) of that Act^(b)(persons qualifying for advice and assistance) applies;
 - (d) the child is provided with accommodation at a school to which he or she is admitted in accordance with a statement of special educational needs made under section 324 of the Education Act 1996^(c)(statement of special educational needs); or
 - (e) the child requires accommodation in a care home, a children's home or an independent hospital to meet the child's continuing care needs.
- (3) This sub-paragraph applies to a child if—
- (a) the child is provided with—
 - (i) services which consist of or include the provision of accommodation situated in the area of another CCG or of a Local Health Board, under arrangements made by the CCG in the exercise of its commissioning functions (by itself or jointly with a local authority), or
 - (ii) such services under arrangements made by the local authority and immediately before those arrangements were made the CCG was responsible for the child under section 3(1A) of the 2006 Act; and
 - (b) the child is both—
 - (i) resident in that accommodation, and
 - (ii) would not be a person for whom the CCG is responsible under section 3(1A)(a) of the 2006 Act.

5. A person falls within this paragraph if—

- (a) the CCG has made an arrangement in the exercise of its commissioning functions (by itself or jointly with a local authority) by virtue of which immediately before attaining 18 the person was provided with services to meet his or her continuing care needs;
- (b) those services consist of or include the provision of the following accommodation and services to meet the person's continuing care needs—
 - (i) accommodation in a care home, a children's home or an independent hospital situated in the area of another CCG, and
 - (ii) nursing and another service which is a planned service, as part of the health service to meet his or her continuing care needs;
- (c) the person is resident in that accommodation and continues to need that planned service (or those planned services), and
- (d) the person would not be a person for whom the CCG is responsible under section 3(1A)(a) of the 2006 Act.

6. A person falls within this paragraph if—

- (a) a Primary Care Trust has made an arrangement before the relevant date in the exercise of its functions by virtue of regulation 3 of the National Health Service (Functions of Strategic Health Authorities and Primary Care Trusts and Administration Arrangements)(England) Regulations 2002^(d) by virtue of which the person was provided with services to meet his or her continuing care needs;

(a) Section 23A was inserted into the Children Act 1989 by section 2(1) and (4) of the Children (Leaving Care) Act 2000 (c.35).

(b) Section 24(1A) and (1B) were inserted into the Children Act 1989 by section 139(1) of, and paragraphs 54, 60(a) and 60(b) of Schedule 3 to the Adoption and Children Act 2002 (c.38).

(c) 1996 c. 56. Section 324 was amended by section 140(1) of, and paragraph 77(b) of Schedule 30 to, the School Standards and Framework Act 1998 (c. 31) and section 9 of the Special Educational Needs and Disability Act 2001 (c. 10).

(d) S.I. 2002/2375 relevant amending instruments S.I. 2006/359 and S.I. 2010/2649.

- (b) the rights and liabilities under that arrangement are transferred to the CCG by virtue of a scheme made under section 300 of the 2012 Act (transfer schemes);
- (c) the person continues to need the provision of the following accommodation and services to meet the person's continuing care needs—
 - (i) accommodation in a care home or independent hospital situated in the area of another CCG, and
 - (ii) at least one planned service (other than a service consisting only of NHS-funded nursing care) which is connected to the provision of such accommodation (whether or not the accommodation is arranged by the CCG); and
- (d) the person would not be a person for whom the CCG is responsible under section 3(1A)(a) of the 2006 Act.

7. A child falls within this paragraph if—

- (a) a Primary Care Trust has made an arrangement on or before 31st March 2013 in the exercise of its functions by virtue of regulation 3 of the National Health Service (Functions of Strategic Health Authorities and Primary Care Trusts and Administration Arrangements) (England) Regulations 2002 by virtue of which the child was provided with services to meet his or her continuing care needs;
- (b) the rights and liabilities under that arrangement are transferred to the CCG by virtue of a scheme made under section 300 of the 2012 Act;
- (c) the child continues to need services consisting of or including the provision of accommodation in a care home, a children's home or an independent hospital situated in the area of another CCG and nursing and another service which is a planned service as part of the health service to meet his or her continuing care needs; and
- (d) the child would not be a person for whom the CCG is responsible under section 3(1A)(a) of the 2006 Act.

8.—(1) A child falls within this paragraph if—

- (a) a local authority has made an arrangement before the relevant date by virtue of which the child is provided with accommodation at a school in the area of another CCG or a Local Health Board, to which the child is admitted in accordance with a statement of special educational needs made under section 324 of the Education Act 1996;
- (b) immediately before the child was accommodated at that school the child was either—
 - (i) provided with primary medical services by a person who is now a member of the CCG; or
 - (ii) usually resident in the area of the CCG and not provided with primary medical services by a person who is now a member of the CCG; and
- (c) the child would not be a person for whom the CCG is responsible under section 3(1A)(a) of the 2006 Act.

SCHEDULE 2

Regulation 6

Prescribed dental services

1. Oral surgery.
2. Restorative dentistry.
3. Paedodontic/paediatric dentistry.
4. Orthodontics.
5. Oral and maxillofacial surgery.

6. Endodontics.
7. Periodontics.
8. Prosthodontics.
9. Oral medicine.
10. Oral microbiology.
11. Oral and maxillofacial pathology.
12. Dental and maxillofacial radiology.
13. Special care dentistry.

SCHEDULE 3

Regulation 10

Services in respect of persons detained in specified accommodation

PART 1

Secure children's homes to which regulation 10(2)(b) does not apply

1. Atkinson Secure Children's Home
2. Beechfield Secure Children's Home
3. Clare Lodge Secure Children's Home
4. Kylloe Secure Children's Home
5. Lansdowne Secure Children's Home
6. Leverton Secure Children's Home
7. St. Catherine's Secure Children's Home

PART 2

Secure training centres and immigration removal centres

Table 1 – Secure training centres

<i>Name of centre</i>	<i>Specified date</i>
Hassockfield Secure Training Centre	From 1st April 2014
Medway Secure Training Centre	From 1st April 2014
Rainsbrook Secure Training Centre	From 1st April 2014

Table 2 – Immigration removal centres

<i>Name of centre</i>	<i>Specified Date</i>
Brook House Immigration Removal Centre	From 1st April 2014
Campsfield House Immigration Removal Centre	From 1st April 2014
Colnbrook Immigration Removal Centre	From 1st April 2013

Dover Immigration Removal Centre	From 1st April 2013
Harmondsworth Immigration Removal Centre	From 1st April 2013
Haslar Immigration Removal Centre	From 1st April 2013
Morton Hall Immigration Removal Centre	From 1st April 2013
Tinsley House Immigration Removal Centre	From 1st April 2014
Yarls Wood Immigration Removal Centre	From 1st April 2013

SCHEDULE 4

Regulations 7, 10 and 11

Services for rare and very rare conditions

Interpretation

1. For the purposes of this Schedule—

- (a) an individual is a child if they have not yet attained the age of 18 years old;
- (b) an individual is a young person if they are aged 13 years old or over but have not yet attained the age of 21 years old; and
- (c) an individual is an adult if they are aged 18 years old or over,

unless, for the purposes of a service specified in this Schedule, the Board, or the person providing such a service pursuant to a commissioning contract with the Board, considers on clinical grounds that an individual should otherwise be treated as a child, a young person or an adult.

The services

- 2. Adult ataxia telangiectasia services.
- 3. Adult congenital heart disease services.
- 4. Adult highly specialist pain management services.
- 5. Adult highly specialist respiratory services.
- 6. Adult highly specialist rheumatology services.
- 7. Adult secure mental health services.
- 8. Adult specialist cardiac services.
- 9. Adult specialist eating disorder services.
- 10. Adult specialist endocrinology services.
- 11. Adult specialist intestinal failure services.
- 12. Adult specialist neurosciences services.
- 13. Adult specialist ophthalmology services.
- 14. Adult specialist orthopaedic services.
- 15. Adult specialist pulmonary hypertension services.
- 16. Adult specialist renal services.
- 17. Adult specialist services for patients infected with HIV.
- 18. Adult specialist vascular services.
- 19. Adult thoracic surgery services.

20. Alkaptonuria service.
21. Alström syndrome service.
22. Ataxia telangiectasia service for children.
23. Autoimmune paediatric gut syndromes service.
24. Autologous intestinal reconstruction service for adults.
25. Bardet-Biedl syndrome service.
26. Barth syndrome service.
27. Beckwith-Wiedemann syndrome with macroglossia service.
28. Behcet's syndrome service.
29. Bladder exstrophy service.
30. Blood and marrow transplantation services.
31. Bone anchored hearing aid services.
32. Breast radiotherapy injury rehabilitation service.
33. Child and adolescent mental health services – Tier 4.
34. Choriocarcinoma service.
35. Chronic pulmonary aspergillosis service.
36. Cleft lip and palate services.
37. Cochlear implantation services.
38. Complex childhood osteogenesis imperfecta service.
39. Complex Ehlers Danlos syndrome service.
40. Complex neurofibromatosis type 1 service.
41. Complex spinal surgery services.
42. Complex tracheal disease service.
43. Congenital hyperinsulinism service.
44. Craniofacial service.
45. Cryopyrin associated periodic syndrome service.
46. Cystic fibrosis services.
47. Diagnostic service for amyloidosis.
48. Diagnostic service for primary ciliary dyskinesia.
49. Diagnostic service for rare neuromuscular disorders.
50. Encapsulating peritoneal sclerosis treatment service.
51. Epidermolysis bullosa service.
52. Extra corporeal membrane oxygenation service for adults.
53. Extra corporeal membrane oxygenation service for neonates, infants and children with respiratory failure.

54. Ex-vivo partial nephrectomy service.
55. Fetal medicine services.
56. Gender identity development service for children and adolescents.
57. Gender identity disorder services.
58. Heart and lung transplantation service (including bridge to transplant using mechanical circulatory support).
59. Highly specialist adult urinary and gynaecological surgery services.
60. Highly specialist allergy services.
61. Highly specialist colorectal surgery services.
62. Highly specialist dermatology services.
63. Highly specialist metabolic disorder services.
64. Highly specialist pain management services for children and young people.
65. Highly specialist palliative care services for children and young people.
66. Highly specialist services for adults with infectious diseases.
67. Hyperbaric oxygen treatment services.
68. Insulin-resistant diabetes service.
69. Islet transplantation service.
70. Liver transplantation service.
71. Lymphangiomyomatosis service.
72. Lysosomal storage disorder service.
73. Major trauma services.
74. McArdle's disease service.
75. Mental health service for deaf children and adolescents.
76. Middle ear implantable hearing aid services.
77. Neurofibromatosis type 2 service.
78. Neuromyelitis optica service.
79. Neuropsychiatry services.
80. Ocular oncology service.
81. Ophthalmic pathology service.
82. Osteo-odonto-keratoprosthesis service for corneal blindness.
83. Paediatric and perinatal post mortem services.
84. Paediatric cardiac services.
85. Paediatric intestinal pseudo-obstructive disorders service.
86. Pancreas transplantation service.
87. Paroxysmal nocturnal haemoglobinuria service.

88. Positron Emission Tomography – Computed Tomography services.
89. Primary ciliary dyskinesia management service.
90. Primary malignant bone tumours service.
91. Proton beam therapy service.
92. Pseudomyxoma peritonei service.
93. Pulmonary hypertension service for children.
94. Pulmonary thromboendarterectomy service.
95. Radiotherapy services.
96. Rare mitochondrial disorders service.
97. Reconstructive surgery service for adolescents with congenital malformation of the female genital tract.
98. Retinoblastoma service.
99. Secure forensic mental health service for young people.
100. Severe acute porphyria service.
101. Severe combined immunodeficiency and related disorders service.
102. Severe intestinal failure service.
103. Severe obsessive compulsive disorder and body dysmorphic disorder service.
104. Small bowel transplantation service.
105. Specialist burn care services.
106. Specialist cancer services.
107. Specialist cancer services for children and young people.
108. Specialist dentistry services for children and young people.
109. Specialist ear, nose and throat services for children and young people.
110. Specialist endocrinology and diabetes services for children and young people.
111. Specialist gastroenterology, hepatology and nutritional support services for children and young people.
112. Specialist genetic services.
113. Specialist gynaecology services for children and young people.
114. Specialist haematology services for children and young people.
115. Specialist haemoglobinopathy services.
116. Specialist immunology services for patients with deficient immune systems.
117. Specialist mental health services for deaf adults.
118. Specialist morbid obesity services.
119. Specialist neonatal care services.
120. Specialist neuroscience services for children and young people.

121. Specialist ophthalmology services for children and young people.
122. Specialist orthopaedic surgery services for children and young people.
123. Specialist paediatric intensive care services.
124. Specialist paediatric liver disease service.
125. Specialist perinatal mental health services.
126. Specialist plastic surgery services for children and young people.
127. Specialist rehabilitation services for patients with highly complex needs.
128. Specialist renal services for children and young people.
129. Specialist respiratory services for children and young people.
130. Specialist rheumatology services for children and young people.
131. Specialist services for children and young people with infectious diseases.
132. Specialist services for complex liver, biliary and pancreatic diseases in adults.
133. Specialist services for haemophilia and other related bleeding disorders.
134. Specialist services for severe personality disorder in adults.
135. Specialist services to support patients with complex physical disabilities.
136. Specialist surgery for children and young people.
137. Specialist urology services for children and young people.
138. Spinal cord injury services.
139. Stem cell transplantation service for juvenile idiopathic arthritis and related connective tissue disorders.
140. Stickler syndrome diagnostic service.
141. Vein of Galen malformation service.
142. Veterans' post traumatic stress disorder programme.
143. Wolfram syndrome service.
144. Xeroderma pigmentosum service.

SCHEDULE 5

Regulation 25(3)

Persons disqualified from being a chair, CCG member or social services authority member of a review panel

1. A Member of Parliament, Member of the European Parliament or member of the London Assembly.

2.—(1) An individual who, by arrangement with a CCG, provides it with any service or facility in order to support that CCG in discharging its commissioning functions, or an employee or member (including shareholder) of, or a partner in, a body which does so.

(2) The services and facilities mentioned in sub-paragraph (1) do not include services commissioned by a CCG in the exercise of its commissioning functions.

3. A person who, within the period of five years immediately preceding the date of the proposed appointment, has been convicted—

- (a) in the United Kingdom of any offence; or
- (b) outside the United Kingdom of an offence which, if committed in any part of the United Kingdom, would constitute a criminal offence in that part,

and, in either case, the final outcome of the proceedings was a sentence of imprisonment (whether suspended or not) for a period of not less than three months without the option of a fine.

4. A person who is subject to a bankruptcy restrictions order or an interim bankruptcy restrictions order under Schedule 4A to the Insolvency Act 1986(a), sections 56A to 56K of the Bankruptcy (Scotland) Act 1985(b) or Schedule 2A to the Insolvency (Northern Ireland) Order 1989(c) (which relate to bankruptcy restrictions orders and undertakings).

5.—(1) A person who has been dismissed within the period of five years immediately preceding the date of the proposed appointment, otherwise than because of redundancy, from paid employment by any of the following—

- (a) the Board;
- (b) a CCG;
- (c) a social services authority;
- (d) a Strategic Health Authority(d);
- (e) a Primary Care Trust(e);
- (f) an NHS trust(f);
- (g) an NHS foundation trust;
- (h) a Special Health Authority(g);
- (i) a Local Health Board established under section 11 of the National Health Service (Wales) Act 2006;
- (j) a Health Board or Special Health Board constituted under the National Health Service (Scotland) Act 1978(h);
- (k) a Scottish NHS trust established under section 12A of the National Health Service (Scotland) Act 1978(i);
- (l) a Health and Social Services Board constituted under the Health and Personal Social Services (Northern Ireland) Order 1972(j);

(a) 1986 c. 45. Schedule 4A was inserted by the Enterprise Act 2002 (c. 40), Schedule 20.

(b) 1985 c. 66. Sections 56A to 56K were inserted by the Bankruptcy and Diligence etc. (Scotland) Act 2007 (asp 3), section 2(1).

(c) S.I. 1989/2405 (N.I. 19). Schedule 2A was inserted by S.I. 2005/1455 (N.I. 10).

(d) Strategic Health Authorities are continued in existence or established under section 13 of the 2006 Act. They are abolished by section 33 of the 2012 Act.

(e) Primary Care Trusts are continued in existence or established under section 18 of the 2006 Act. They are abolished by section 34 of the 2012 Act.

(f) NHS trusts are established under section 25 of the 2006 Act or section 18 of the National Health Service (Wales) Act 2006 (c. 42). NHS Trusts in England are abolished by section 179 of the 2012 Act.

(g) Special Health Authorities are established under section 28 of the 2006 Act or section 22 of the National Health Service (Wales) Act 2006.

(h) 1978 c. 29. Section 2 was amended by paragraph 1 of Schedule 7 to the Health and Social Services Adjudications Act 1983 (c. 41), section 28 of, and paragraph 19(1) of Schedule 9 and paragraph 1 of Schedule 10 to, the National Health Service and Community Care Act 1990 (c. 19), paragraph 1(2) of Schedule 1 to the National Health Service Reform (Scotland) Act 2004 (asp 7), paragraph 2(2) of Schedule 2 to the Smoking, Health and Social Care (Scotland) Act 2005 (asp 13) and section 2(1) of the Health Boards (Membership and Elections) (Scotland) Act 2009 (asp 5).

(i) Section 12A was inserted by section 31 of the National Health Service and Community Care Act 1990 and amended by paragraph 34 of Schedule 2 to the National Health Service (Primary Care) Act 1997 (c. 46) and sections 46(1) and 48 of, and paragraph 45 of Schedule 4 to, the Health Act 1999 (c. 8).

(j) S.I. 1972/1265 (N.I. 14). Health and Social Services Boards were dissolved by section 1(1) of the Health and Social Care (Reform) Act (Northern Ireland) 2009.

- (m) the Care Quality Commission established by section 1 of the Health and Social Care Act 2008(a);
- (n) the Health Protection Agency established by section 1 of the Health Protection Agency Act 2004(b);
- (o) Monitor(c);
- (p) the Wales Centre for Health established by section 2 of the Health (Wales) Act 2003(d);
- (q) the Common Services Agency for the Scottish Health Service constituted by section 10 of the National Health Service (Scotland) Act 1978(e);
- (r) Healthcare Improvement Scotland, established by section 10A of the National Health Service (Scotland) Act 1978(f);
- (s) the Scottish Dental Practice Board constituted under section 4 of the National Health Service (Scotland) Act 1978(g);
- (t) the Northern Ireland Central Services Agency for the Health and Social Services established under the Health and Personal Social Services (Northern Ireland) Order 1972(h);
- (u) the Regional Health and Social Care Board established under section 7 of the Health and Social Care (Reform) Act (Northern Ireland) 2009(i);
- (v) the Regional Agency for Public Health and Wellbeing established under section 12 of the Health and Social Care (Reform) Act (Northern Ireland) 2009;
- (w) the Regional Business Services Organisation established under section 14 of the Health and Social Care (Reform) Act (Northern Ireland) 2009;
- (x) Health and Social Care trusts (formerly known as Health and Social Services trusts), established under the Health and Personal Social Services (Northern Ireland) Order 1991(j);
- (y) Special health and social care agencies (formerly known as Special health and social services agencies), established under the Health and Personal Social Services (Special Agencies) (Northern Ireland) Order 1990(k);
- (z) the Patient and Client Council established under section 16 of the Health and Social Care (Reform) Act (Northern Ireland) 2009; and
- (aa) the Health and Social Care Regulation and Quality Improvement Authority (formerly known as The Northern Ireland Health and Personal Social Services Regulation and Improvement Authority), established under the Health and Personal Social Services (Quality Improvement and Regulation) (Northern Ireland) Order 2003(l).

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- (a) 2008 c. 14.
 - (b) 2004 c. 17. The Health Protection Agency is abolished by section 56 of the 2012 Act.
 - (c) "Monitor" is the new name given to the Independent Regulator of NHS Foundation Trusts: see section 61 of the 2012 Act, and generally, Chapter 1 of Part 3 of that Act.
 - (d) 2003 c. 4. The Wales Centre for Health is abolished under S.I. 2009/2653 (W215).
 - (e) Section 10 was amended by paragraph 2 of Schedule 6 to the Health Services Act 1980 (c. 53), paragraph 1 of Schedule 10 to the National Health Service and Community Care Act 1990, paragraph 44 of Schedule 8 to the Health Act 1999 (c. 8) and paragraph 2(4) of Schedule 2 to the Smoking, Health and Social Care (Scotland) Act 2005 (asp 13).
 - (f) Section 10A was inserted by section 108 of the Public Services Reform (Scotland) Act 2010 (asp 8).
 - (g) Section 4 was amended by section 12(3) of, and Schedule 3 to, the Health and Medicines Act 1988 (c. 49) and paragraph 2(3) of Schedule 2 to the Smoking, Health and Social Care (Scotland) Act 2005.
 - (h) The Northern Ireland Central Services Agency for the Health and Social Services was dissolved by section 1(1) of the Health and Social Care (Reform) Act (Northern Ireland) 2009.
 - (i) 2009 c. 1 (N.I.).
 - (j) S.I. 1991/194 (N.I. 1). Health and Social Services trusts established under Article 10 of S.I. 1991/194 (N.I.) were renamed Health and Social Care trusts under section 1(3) of the Health and Social Care (Reform) Act (Northern Ireland) 2009.
 - (k) S.I. 1990/247 (N.I. 3). Special health and social services agencies established under Article 10 of the Health and Personal Social Services (Special Agencies) (Northern Ireland) Order 1990 were renamed Special health and social care agencies under section 1(3) of the Health and Social Care (Reform) Act (Northern Ireland) 2009.
 - (l) S.I. 2003/431 (N.I. 9). The Northern Ireland Health and Personal Social Services Regulation and Improvement Authority established under Article 10 of S.I. 2003/431 (N.I. 9) was renamed The Health and Social Care Regulation and Quality Improvement Authority under section 1(2) of the Health and Social Care (Reform) Act (Northern Ireland) 2009.

(2) For the purposes of paragraph (1), a person is not to be treated as having been in paid employment by reason only of having been—

- (a) in the case of an NHS foundation trust, the chairman, a governor or a non-executive director of the trust;
- (b) in the case of a CCG, the chair or a member of the governing body of that CCG; or
- (c) in the case of any other NHS body, the chairman or chair, or a member or a director of the NHS body in question.

6. A person's term of office as the chairman or chair or as a member, director or governor of any of the bodies specified in paragraph 5(1) has been terminated on the grounds—

- (a) that it was not in the interests of, or conducive to the good management of, that body that they should continue to hold office;
- (b) that it was not in the interests of the health service that they should continue to hold office;
- (c) of non-attendance at meetings;
- (d) of non-disclosure of a pecuniary interest;
- (e) of misbehaviour, misconduct or failure to carry out the person's duties.

7. A health care professional or other professional person who has at any time been subject to an investigation or proceedings, by any body which regulates or licenses the profession concerned ("the regulatory body"), in connection with the person's fitness to practise or any alleged fraud, the final outcome of which was—

- (a) the person's suspension from a register held by the regulatory body, where that suspension has not been terminated;
- (b) the person's erasure from such a register, where the person has not been restored to the register;
- (c) a decision by the regulatory body which had the effect of preventing the person from practising the profession in question, where that decision has not been superseded; or
- (d) a decision by the regulatory body which had the effect of imposing conditions on the person's practice of the profession in question, where those conditions have not been lifted.

8. A person who is subject to—

- (a) a disqualification order or disqualification undertaking under the Company Directors Disqualification Act 1986(a) or the Company Directors Disqualification (Northern Ireland) Order 2002(b); or
- (b) an order made under section 429(2) of the Insolvency Act 1986(c) (disabilities on revocation of administration order against an individual).

9. A person who has at any time been removed from the office of charity trustee or trustee for a charity by an order made by the Charity Commissioners for England and Wales(d), the Charity Commission, the Charity Commission for Northern Ireland or the High Court, on the grounds of misconduct or mismanagement in the administration of the charity for which the person was responsible, to which the person was privy, or which the person by their conduct contributed to or facilitated.

(a) 1986 c. 46.

(b) S.I. 2002/3150 (N.I. 4).

(c) 1986 c. 45. The original subsections (1) and (2) were substituted by paragraph 3(2) of Schedule 16 to the Tribunals, Courts and Enforcement Act 2007 (c. 15), and subsection (2) was amended by paragraph 15 of Schedule 23 to the Enterprise Act 2002 (c. 40).

(d) The Charity Commissioners for England and Wales were replaced by the Charity Commission: section 6 of the Charities Act 2006 (c. 50).

10. A person who has at any time been removed, or is suspended, from the management or control of any body under—

- (a) section 7 of the Law Reform (Miscellaneous Provisions) (Scotland) Act 1990^(a) (powers of the Court of Session to deal with the management of charities); or
- (b) section 34(5)(e) or (ea) of the Charities and Trustee Investment (Scotland) Act 2005^(b) (powers of the Court of Session to deal with the management of charities).

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations 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”). They are made under powers in the National Health Service Act 2006 (c.41) (“the 2006 Act”) and the Mental Health Act 1983 (“the 1983 Act”), as amended by the Health and Social Care Act 2012 (c. 7) (“the 2012 Act”), and powers in the 2012 Act.

Part 2 of the Regulations makes provision in respect of persons for whom a CCG must or may commission services. Section 3(1A) of the 2006 Act (inserted by section 13(3) of the 2012 Act) provides for a CCG to have the duty to commission services for persons who are provided with primary medical services by a member of the CCG, and persons who usually reside in the CCG’s area and who are not provided with primary medical services by a member of any CCG. Section 3A of the 2006 Act (inserted by section 14 of the 2012 Act) makes corresponding provision in relation to further services which a CCG has the power, but not the duty, to commission. By virtue of section 3(1B) of the 2006 Act, regulations may also provide for additional categories of person for whom a CCG has the duty to commission services under section 3 of that Act, and the power to commission certain other services under section 3A of that Act. Regulation 2 and Schedule 1 therefore provide for the additional categories of person for whom a CCG has the duty to commission services under section 3 of the 2006 Act, and the power to commission other services under section 3A of that Act. The list of such persons is in paragraph 2 of Schedule 1.

Part 3 of the Regulations is made under section 3B(1) of the 2006 Act. They make provision in respect of the services which the Board is required to arrange, to the extent which it considers necessary to meet all reasonable requirements, for the provision of as part of the health service. The Board is established under section 1H of the 2006 Act as inserted by section 9 of the 2012 Act. Regulation 6(a) requires the Board to arrange for the provision of dental services that are generally provided outside of a general dental practice or hospital setting such as in a community hospital or clinic, a health centre or in a person’s home. Regulation 6(b) and Schedule 2 require the Board to arrange for the provision, as part of the health service, of the dental services that are specified in that Schedule.

Regulations 7 to 9 require the Board to make arrangements for the provision of secondary care services, community services and the services specified in Schedule 4 to serving members of the armed forces and their families who are registered with Defence Medical Services. Secondary care services are specialist health services which are provided on referral from a primary care practitioner. Community services include such health services as district nursing, contraceptive services, physiotherapy and home oxygen services. The services specified in Schedule 4 are specialised health services for people suffering from rare and very rare conditions. Regulation 7 also requires the Board to make arrangements for the provision of infertility treatment to serving members of the armed forces. Regulation 8 requires the Board to provide infertility treatment to severely injured members of the armed forces and veterans who have been injured in service and who are in receipt of compensation under the Armed Forces Compensation Scheme 2011 if, as a result of the injury sustained, they suffer from infertility and wish to receive infertility treatment, and they are eligible for and have been accepted for such treatment. Regulation 9 makes provision

(a) 1990 c. 40. Section 7 was repealed by paragraph 7(b) of Schedule 4 to the Charities and Trustee Investment (Scotland) Act 2005 (asp 10).

(b) 2005 (asp 10). Section 34 was amended by section 122 of the Public Services Reform (Scotland) Act 2010 (asp 8).

for infertility treatment to be provided by the Board in specified circumstances to the named partner of a serviceman or veteran referred to in regulation 7(1)(a) or 8(1) who has died or has become mentally incapacitated.

Regulation 10 and Schedule 3 require the Board to make arrangements for the provision of secondary care services and the services specified in Schedule 4 to prisoners and also to persons who have been detained in the other accommodation described in paragraph (2). Regulation 11 and Schedule 4 require the Board to make arrangements for the provision of the services specified in Schedule 4. Regulation 12 requires the Board to make arrangements for the continued provision of the health services currently provided by certain Independent Sector Treatment Centres pursuant to specified agreements with the Secretary of State for Health, including diagnostic and assessment services (such as screening and imaging services) and elective services (including trauma surgery, general surgery and pain management). Regulation 13 requires the Board to make arrangements for the provision of services for the specialist mental health assessment and management of persons with mental health problems who may present a risk to prominent people or locations.

Part 4 provides for the circumstances in which the duty imposed on a clinical commissioning group under section 117 of the 1983 Act, to arrange for the provision of after-care services for a person to whom that section applies, is instead be imposed on another clinical commissioning group or on the Board.

Part 5 of the Regulations makes provision as to matters which must be included in contracts to commission health care services entered into by the Board or clinical commissioning groups. Regulation 16 requires that such contracts must contain terms and conditions relating to the circumstances in which an apology and particular information must be provided where there has been a patient safety incident during the provision of health care services (“duty of candour provisions”). Regulation 17 also requires the Board to draft model terms and conditions in respect of the duty of candour provisions, and it requires both the Board and clinical commissioning groups to incorporate such terms and conditions in any commissioning contract entered into. Regulation 17 requires the Board to draft such other terms and conditions as it considers appropriate, and also empowers the Board to require clinical commissioning groups to incorporate any such further terms and conditions into any commissioning contract it enters into. Regulation 18 requires the Board to consult particular persons or bodies, such as Monitor and the Secretary of State, before drafting model terms and conditions, or revising them in any significant way.

Part 6 makes provision about NHS Continuing Healthcare and NHS funded nursing care. Regulation 21 imposes duties on the Board and clinical commissioning groups in relation to the assessment of need for NHS Continuing Healthcare, and, where appropriate, as to the provision of such care. Regulation 22 imposes requirements to work collaboratively with Local Authorities’ social services as regards assessments for NHS Continuing Healthcare, in particular to ensure the continuity of services for persons who become eligible for, or cease to be eligible for, NHS Continuing Healthcare. Regulation 23 makes provision in relation to the Board’s duty to organise a review where a person is dissatisfied with the procedure followed in reaching a decision as to eligibility for NHS Continuing Healthcare, or the decision itself. Regulations 24 to 27, and Schedule 5, make provision in respect of the appointment and term of office of members of a review panel, the circumstances in which a person is disqualified for appointment and the circumstances in which such an appointment can be terminated. Regulation 28 makes provision in respect of the circumstances in which the Board or a clinical commissioning group must arrange for the assessment of a person’s need for nursing care, and payments that must be made in respect of nursing care where a person is found to have such a need. Regulations 29 and 30 afford protection to persons in receipt of historical rates of payment in respect of nursing care, preserving the position under the National Health Service (Nursing Care in Residential Accommodation) (England) Directions 2007. Regulation 32 revokes Directions that underpinned the previous system for NHS Continuing Healthcare and NHS-funded nursing care, and makes transitional provision in respect of matters that are on-going immediately before 1st April 2013.

The provisions in Part 7 underpin rights set out in the NHS Constitution. The Constitution states “You have the right to drugs and treatments that have been recommended by NICE for use in the

NHS, if your doctor says they are clinically appropriate for you,” and “You have the right to expect local decisions on funding of drugs and other treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you.” Part 7 imposes duties on the Board or clinical commissioning groups to have arrangements in place for ensuring that those bodies comply with relevant NICE recommendations, and where there is no relevant NICE recommendation, for making decisions and adopting policies on whether a particular healthcare intervention is to be funded (regulation 34), including a duty to give reasons for particular policies or decisions as to whether or not to fund a healthcare intervention (regulation 35). The Board or clinical commissioning groups must have written information on the arrangements the body has in place and publish them on its website, and have them available at the main office of the body for inspection (regulation 36). Regulation 37 makes transitional provision in respect of matters on-going under the Directions to Primary Care Trusts and NHS trusts concerning decisions about drugs and other treatments 2009 immediately before 1st April 2013.

The provisions in Part 8 underpin rights set out in the NHS Constitution, namely the right to “choose the organisation that provides your NHS care when you are referred for your first outpatient appointment with a service led by a consultant”, subject to certain exceptions. Part 8 of the Regulations is made under both section 6E of the 2006 Act and section 75 of the 2012 Act, the effect being that, by virtue of section 76 of the 2012 Act, enforcement powers may be conferred on Monitor in relation to the provisions in Part 8. Part 8 imposes a duty on the Board and clinical commissioning groups to ensure that a person for whom it has responsibility and who requires an elective referral is able to choose any clinically appropriate health service provider as regards the first outpatient appointment with a consultant or a member of a consultant’s team, as long as the Board or any clinical commissioning group has a commissioning contract with such a provider for the service required (regulation 39): it also imposes a duty on the Board and clinical commissioning groups to offer a choice of any clinically appropriate team led by a named consultant who is employed or engaged by that provider. Regulation 39 also imposes a duty on the Board and clinical commissioning groups to offer a choice of a team led by any clinically appropriate health care professional who is employed or engaged by the health service provider to whom the patient is referred for mental health services, where it is an elective referral. Regulations 40 and 41 set out the services in respect of which, and persons in relation to whom, the duties to offer a choice do not apply. Regulation 42 imposes duties on the Board and clinical commissioning groups as to the publication and promotion of information about choice under the arrangements made by them. Regulation 43 makes transitional provision in respect of matters on-going under the Primary Care Trusts (Choice of Secondary Care Provider) Directions 2009 immediately before 1st April 2013: prior to 1st April 2013, the Directions formed the legal basis for the NHS Constitution right but from 1st April 2013, Part 8 of the Regulations forms the legal basis of this right.

The provisions in Part 9 underpin rights set out in the NHS Constitution, namely the right to access services within maximum waiting times, or for the NHS to take all reasonable steps to offer a range of alternative providers if this is not possible. Regulation 45 imposes a duty to make arrangements to ensure that treatment appropriate to the reason for an elective referral is provided within eighteen weeks of receipt of notice of such a referral in a specified percentage of cases. Regulations 47 and 48 impose a duty to offer an alternative provider of health care services in particular circumstances where a person is not going to receive appropriate treatment within the eighteen week period, and regulation 49 sets out the exceptions to the duty, for example where a patient has decided they do not want to commence treatment. Regulation 50 requires the Board and clinical commissioning groups to have regard to a guidance document entitled “The Referral to Treatment Consultant-led Waiting Times Rules Suite” published in January 2012 in carrying out its duties under regulations 45 to 48. Regulation 51 sets out the circumstances in which a clinical commissioning group must notify the Board that a particular person will not commence treatment with the eighteen week period. Regulation 52 imposes a duty to make arrangements to ensure that where a person is urgently referred for suspected cancer, that person is provided treatment for suspected cancer within two weeks of the notice of referral being received by the health service provider in a particular percentage of cases. Regulation 53 imposes a duty to offer

an alternative provider of health care services in particular circumstances where a person is not going to receive appropriate treatment in respect of suspected cancer within the two week period. Regulation 54 imposes obligations on clinical commissioning groups to establish a service providing advice and assistance to persons for whom it has responsibility and who benefit from the waiting times provisions in Part 9. Regulation 55 makes transitional provision in respect of matters on-going under the Primary Care Trusts and Strategic Health Authorities (Waiting Times) Directions 2012 which came into force on 1st April 2010, immediately before 1st April 2013.

Part 10 imposes an obligation on the Board and clinical commissioning groups in respect of the funding of certain disease modifying therapies for Multiple Sclerosis. It ensures that these bodies continue to fund such therapies in accordance with an arrangement made between the Department of Health, the National Assembly for Wales, the Scottish Ministers, the Northern Ireland Department for Health, Social Security and Public Safety, Biogen Idec Inc., Bayer PLC, Merck Serono Limited, and Teva Pharmaceutical Industries Limited together with Aventis Pharma Limited, dated 1st February 2002, for the supply and administration of products for the treatment of multiple sclerosis.

Part 11 concerns duties of the Board and CCGs in relation to the amount of financial resource those bodies may use in respect of administration. Section 223D(3) of the 2006 Act (as inserted by section 24 of the 2012 Act) provides that the Board must ensure that the total revenue resource use in a financial year by the Board and CCGs taken together does not exceed the amount specified by the Secretary of State. Section 223E then provides for additional controls on revenue resource use, including a provision at section 223E(3) that the Secretary of State may direct the Board to ensure that total revenue resource use, and the Board's revenue resource use, in a financial year attributable to such prescribed matters relating to administration as are specified in the directions do not exceed the amounts specified. Section 223J(3), when read with section 223J(6), then gives the Board a consequential power to direct a CCG to ensure that its revenue resource use in a financial year attributable to those prescribed matters relating to administration does not exceed an amount specified. Part 11 of the Regulations prescribes the matters relating to administration which may apply for the purposes of those directions. Paragraph (3) of regulation 2 specifies that the making of certain payments cannot be included as matters relating to administration for these purposes.

A full impact assessment has been produced in relation to the provisions of the 2012 Act and a copy is available at www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_123583: in respect of Parts 1 to 4, 6, 7 and 9 to 11, no separate impact assessment has been produced as the Parts have no impact on the private sector or civil society organisations. A copy of impact assessments that relate to Part 5 (standing rules: contract terms) and Part 8 (standing rules: choice of health service provider) can be found at www.dh.gov.uk/health/2012/12/duty-candour and www.dh.gov.uk/en/Consultations/Liveconsultations/DH_134221 respectively.

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