



# Care Act 2014

## 2014 CHAPTER 23

VALID FROM 15/07/2014

### PART 3

#### HEALTH

VALID FROM 01/10/2014

### CHAPTER 1

#### HEALTH EDUCATION ENGLAND

##### *Establishment*

#### **96 Health Education England**

- (1) There is to be a body corporate called Health Education England (referred to in this Act as “HEE”).
- (2) Schedule 5 (which includes provision about HEE's constitution, the exercise of its functions and its financial and reporting duties) has effect.
- (3) The Special Health Authority called Health Education England is abolished; and, in consequence of that, the following are revoked—
  - (a) the Health Education England (Establishment and Constitution) Order 2012 (S.I. 2012/1273), and
  - (b) the Health Education England Regulations (S.I. 2012/1290).

*Status: Point in time view as at 07/07/2014. This version of this part contains provisions that are not valid for this point in time.*

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- (4) The Secretary of State may by order provide for the transfer of property, rights and liabilities from that Special Health Authority to HEE; for further provision about an order under this section, see section 118.

*National functions*

**97 Planning education and training for health care workers etc.**

- (1) HEE must perform on behalf of the Secretary of State the duty under section 1F(1) of the National Health Service Act 2006 (planning and delivery of education and training), so far as that duty applies to the functions of the Secretary of State under—
- (a) section 63(1) and (5) of the Health Services and Public Health Act 1968 (instruction for officers of hospital authorities etc.),
  - (b) section 258(1) of the National Health Service Act 2006 (university clinical teaching and research), and
  - (c) such other of the enactments listed in section 1F(3) of that Act as regulations may specify.
- (2) Regulations may—
- (a) provide for the duty under section 1F(1) of the National Health Service Act 2006 to apply to such other functions of the Secretary of State as are specified; and
  - (b) impose on HEE a duty to perform the duty as it applies as a result of provision made under paragraph (a).
- (3) Regulations may provide that the duty under subsection (1) or a duty imposed under subsection (2) may only be performed, or may not be performed, in relation to persons of a specified description.
- (4) In each of the following provisions of the National Health Service Act 2006, after “the Secretary of State” insert “ and Health Education England ”
- (a) section 1F(2) (duty on providers of health services to support system of education and training for health care workers);
  - (b) section 13M (duty on National Health Service Commissioning Board to support that system);
  - (c) section 14Z (duty on clinical commissioning groups to support that system).
- (5) Regulations may give HEE further functions relating to education and training for health care workers.
- (6) HEE may, with the consent of the Secretary of State, carry out other activities relating to—
- (a) education and training for health care workers;
  - (b) the provision of information and advice on careers in the health service.
- (7) After section 63(6) of the Health Services and Public Health Act 1968 insert—
- “(6A) The Secretary of State may make such other payments as the Secretary of State considers appropriate to persons availing themselves of such instruction in England.

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(6B) The Secretary of State may make a payment under subsection (6)(b) or (6A) subject to such terms and conditions as the Secretary of State decides; and the Secretary of State's power to make such a payment includes power to suspend or terminate the payment, or to require repayment, in such circumstances as the Secretary of State decides.”

(8) The power of the Secretary of State under section 63(6) or (6A) of the Health Services and Public Health Act 1968 is exercisable concurrently with HEE; but, in exercising the power, HEE must have regard to any guidance or other information issued by the Secretary of State about its exercise.

(9) “Health care workers” means persons in relation to whom HEE's duty under section 1F(1) of the National Health Service Act 2006 is to be performed.

VALID FROM 01/04/2015

#### **98 Ensuring sufficient skilled health care workers for the health service**

(1) HEE must exercise its functions with a view to ensuring that a sufficient number of persons with the skills and training to work as health care workers for the purposes of the health service is available to do so throughout England.

(2) Regulations may provide that the duty under subsection (1) may only be performed, or may not be performed, in relation to persons of a specified description.

VALID FROM 01/04/2015

#### **99 Quality improvement in education and training, etc.**

(1) HEE must exercise its functions with a view to securing continuous improvement—

- (a) in the quality of education and training provided for health care workers;
- (b) in the quality of health services.

(2) HEE must, in exercising its functions, promote—

- (a) research into matters relating to such of the activities listed in section 63(2) of the Health Services and Public Health Act 1968 (social care services, primary care services and other health services) as are relevant to HEE's functions, and
- (b) the use in those activities of evidence obtained from the research.

(3) In section 2(2) of the Health Act 2009 (bodies required to have regard to NHS Constitution when exercising health service functions), after paragraph (g) insert—

“(h) Health Education England.”

(4) HEE must exercise its functions with a view to securing that education and training for health care workers is provided in a way which promotes the NHS Constitution.

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- (5) “Health services” means health services provided as part of the health service.
- (6) “NHS Constitution” has the meaning given by section 1(1) of the Health Act 2009.

VALID FROM 01/04/2015

## 100 Objectives, priorities and outcomes

- (1) The Secretary of State must publish before the start of each financial year a document which specifies the objectives and priorities that the Secretary of State has set for HEE for that year in relation to the education and training to be provided for health care workers.
- (2) The Secretary of State must also publish at intervals of not more than three years a document (called the “Education Outcomes Framework”) which specifies the outcomes that the Secretary of State has set for HEE to achieve having regard to those objectives and priorities.
- (3) The Secretary of State—
  - (a) may revise a document published under subsection (1) or (2), and
  - (b) if the Secretary of State does so, must publish it as revised.
- (4) HEE must publish a document which—
  - (a) specifies the objectives and priorities that it has set, for the period specified in the document, for the planning and delivery of education and training to health care workers,
  - (b) specifies the outcomes that HEE expects to achieve in that respect during that period having regard to those objectives and priorities, and
  - (c) includes, or refers to a document which includes, guidance for LETBs (see section 103) on the exercise of the function under section 107(1).
- (5) In performing the duty under subsection (4), HEE must have regard, in particular, to its objectives in the longer term in relation to the planning and delivery of education and training to health care workers.
- (6) HEE must ensure that the objectives, priorities and outcomes specified for the purposes of subsection (4)(a) and (b) are consistent with those specified for the purposes of subsections (1) and (2).
- (7) A document under subsection (4) may specify different periods in relation to different categories of health care worker.
- (8) HEE must, before the end of 12 months beginning with the date on which a document under subsection (4) is published—
  - (a) review the document, and,
  - (b) if HEE revises it, publish it as revised.
- (9) HEE may perform the duty under subsection (4) by publishing two or more documents which, taken together, comply with that subsection.
- (10) HEE must seek to achieve the objectives and outcomes and to reflect the priorities specified in any document—

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- (a) published by the Secretary of State under subsection (1), (2) or (3);
- (b) published by HEE under subsection (4) or (8).

VALID FROM 01/04/2015

### **101 Sections 98 and 100: matters to which HEE must have regard**

- (1) In performing the duty under section 98(1) (ensuring sufficient skilled workers for the health service) or the duty under section 100(4) (setting objectives, priorities and outcomes for education and training), HEE must have regard to the following matters in particular—
- (a) the likely future demand for health services and for persons with the skills and training to work as health care workers for the purposes of the health service,
  - (b) the sustainability of the supply of persons with the skills and training to work as such,
  - (c) the priorities that providers of health services have for the education and training of persons wishing to work as such,
  - (d) the mandate published under section 13A of the National Health Service Act 2006,
  - (e) the objectives of the Secretary of State in exercising public health functions (as defined by section 1H of that Act),
  - (f) the priorities that the National Health Service Commissioning Board has for the provision of health services,
  - (g) documents published by the Secretary of State under section 100(1), (2) or (3),
  - (h) the desirability of promoting the integration of health provision with health-related provision and care and support provision,
  - (i) the desirability of enabling health care workers to switch between different posts relating to health provision, health-related provision or care and support provision, and
  - (j) such other matters as regulations may specify.
- (2) In subsection (1), “health provision”, “health-related provision” and “care and support provision” each have the same meaning as in section 3.

VALID FROM 01/04/2015

### **102 Advice**

- (1) HEE must make arrangements for obtaining advice on the exercise of its functions from persons who are involved in, or who HEE thinks otherwise have an interest in, the provision of education and training for health care workers.
- (2) HEE must seek to ensure that it receives representations from the following, in particular, under the arrangements it makes under subsection (1)—
- (a) persons who provide health services;

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- (b) persons to whom health services are provided;
  - (c) carers for persons to whom health services are provided;
  - (d) health care workers;
  - (e) bodies which regulate health care workers;
  - (f) persons who provide, or contribute to the provision of, education and training for health care workers.
- (3) HEE may perform a duty under subsection (2) by seeking to ensure that it receives representations from organisations which represent the persons referred to in the paragraph in question.
- (4) HEE must advise the Secretary of State on such matters relating to its functions as the Secretary of State may request; and a request under this subsection may specify how and when the advice is to be provided.
- (5) “Carer” means an adult who provides or intends to provide care for another person.

#### *Local functions*

VALID FROM 01/04/2015

### **103 Local Education and Training Boards**

- (1) HEE must, in exercise of the power under paragraph 9 of Schedule 5, appoint committees for areas in England, each of which is to be called a Local Education and Training Board (referred to in this Chapter as an “LETB”).
- (2) The main function of an LETB is to exercise on HEE's behalf its functions under sections 97(1) and 98(1) (planning and delivering education for health care workers and ensuring sufficient skilled health care workers in the health service), so far as they are exercisable in or in relation to the LETB's area.
- (3) In carrying out its main function, an LETB must represent the interests of all the persons who provide health services in the area for which the LETB is appointed.
- (4) Subsections (1), (2) and (4) of section 99 (quality improvement in education and training etc.) apply to an LETB in the exercise of its functions as they apply to HEE in the exercise of its functions.
- (5) An LETB may co-operate with another LETB in the exercise of functions; and two or more LETBs may exercise functions jointly.
- (6) HEE may attend any meeting held by an LETB about a matter of concern to HEE.

### **104 LETBs: appointment etc.**

- (1) Where, on an application under this section, HEE is satisfied that the applicants meet the criteria that HEE has set for the purpose (the “appointment criteria”), HEE must appoint the applicants as members of an LETB for such area as HEE considers appropriate.

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- (2) Where, on an application under this section, HEE is satisfied that the applicants meet some (but not all) of the appointment criteria, it may nonetheless appoint the applicants as the members of an LETB for such area and subject to such conditions as HEE considers appropriate.
- (3) The members of an LETB must include—
  - (a) persons who provide health services in the area for which the LETB is appointed,
  - (b) persons who have clinical expertise of a description specified in regulations, and
  - (c) a person who will represent the interests of patients.
- (4) Regulations under paragraph (b) of subsection (3) may require a specified number of members to have the expertise mentioned in that paragraph.
- (5) The following persons are also eligible to be appointed as members of an LETB—
  - (a) persons who, in the area for which the LETB is appointed, provide education or training for health care workers or for persons wishing to work as health care workers, and
  - (b) persons of such other description as HEE may decide.
- (6) A member of HEE is not eligible for membership of an LETB.
- (7) The appointment criteria must include criteria designed to ensure that a majority of the members of an LETB are persons who provide health services in the area for which the LETB in question is appointed.
- (8) If HEE is unable (for reasons beyond its control) to comply with any requirement imposed by this section or regulations under this section to appoint persons of a particular description as members of an LETB, HEE may instead appoint employees of HEE (other than members of HEE).
- (9) On appointing an LETB, HEE must appoint the chair of the LETB; but it may not appoint as chair a person who—
  - (a) provides health services in the area for which the LETB is appointed, or
  - (b) in the area for which the LETB is appointed, provides education or training for health care workers or for persons wishing to work as health care workers.
- (10) HEE must notify applicants under subsection (1) or (2) of the decision on the application and—
  - (a) in the case of an approval of such an application, the area for which the LETB is appointed and the appointment under subsection (9);
  - (b) in the case of a rejection, the reasons for the rejection.
- (11) HEE, having complied with subsection (10), must publish—
  - (a) the decision, and
  - (b) in the case of a rejection, the reasons for the rejection.
- (12) The conditions on which a person is appointed as a member of an LETB must include a condition not to use information obtained in the capacity as such otherwise than for the purposes of the LETB.
- (13) Regulations may make further provision about—

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- (a) the membership of an LETB;
- (b) the removal by HEE of members of an LETB;
- (c) the suspension by HEE of members of an LETB.

(14) Schedule 6 (which includes provision about the area of an LETB, the appointment criteria and the exercise of an LETB's functions) has effect.

### **105 LETBs: co-operation by providers of health services**

- (1) Regulations must require specified commissioners of health services to include in the arrangements under the National Health Service Act 2006 for the provision of such services terms to ensure that a provider of such services—
- (a) co-operates with the LETB for each area in which it provides such services, in such manner and to such extent as the LETB in question may request, in planning the provision of, and in providing, education and training for health care workers;
  - (b) provides the LETB in question with such information as it may request;
  - (c) complies with such other obligations relating to education and training for health care workers as may be specified.
- (2) Duties imposed by regulations under subsection (1) on commissioners of health services are in addition to the duty imposed on such persons by section 1F(2) of the National Health Service Act 2006 (duty to secure that persons providing health services co-operate with the Secretary of State in the discharge of the duty as to education and training).
- (3) Regulations may specify factors to which an LETB must, when proposing to make a request of the type mentioned in subsection (1)(a) or (b), have regard in considering the reasonableness of making the request.
- (4) A reference to a commissioner of health services is a reference to—
- (a) the National Health Service Commissioning Board,
  - (b) a clinical commissioning group, or
  - (c) such other person as arranges for the provision of such services.

VALID FROM 01/04/2015

### **106 Education and training plans**

- (1) An LETB must publish for each financial year a document (called an “education and training plan”) specifying how it proposes to exercise its main function (see section 103(2)).
- (2) The education and training plan of an LETB must specify how the LETB proposes to—
- (a) achieve the objectives and reflect the priorities set by the Secretary of State for the purposes of section 100(1),
  - (b) achieve the objectives and reflect the priorities set by HEE for the purposes of section 100(4)(a),
  - (c) achieve the outcomes set by the Secretary of State for the purposes of section 100(2), and



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- (d) achieve the outcomes set by HEE for the purposes of section 100(4)(b).
- (3) In preparing its education and training plan, an LETB must have regard to—
- (a) the priorities that the providers of health services whom the LETB represents have in relation to the provision in the LETB's area of health services and of education and training for health care workers or persons wishing to become health care workers,
  - (b) the priorities that commissioners of health services in the LETB's area have in relation to those matters,
  - (c) any assessment of relevant needs relating to the LETB's area prepared under section 116 of the Local Government and Public Involvement in Health Act 2007,
  - (d) any joint health and wellbeing strategy relating to the LETB's area prepared under section 116A of that Act, and
  - (e) the LETB's objectives in the longer term in relation to the exercise of the LETB's main function.
- (4) In preparing its education and training plan, an LETB must involve—
- (a) the providers of health services whom the LETB represents,
  - (b) the commissioners of health services in the LETB's area,
  - (c) the Health and Wellbeing Board for that area,
  - (d) such persons as HEE may direct the LETB to involve, and
  - (e) such other persons as the LETB considers appropriate.
- (5) Before publishing its education and training plan (or an amended education and training plan), an LETB must obtain approval of the plan (or the amended plan) from HEE.
- (6) Before giving an approval under subsection (5), HEE may direct the LETB concerned to amend the education and training plan (or the amended education and training plan) as HEE specifies.
- (7) But, in the case of an LETB which meets all the appointment criteria, the only amendments which HEE may direct to be made under subsection (6) are those HEE considers necessary in order to ensure that the LETB achieves the outcomes set by HEE for the purposes of section 100(4)(b).
- (8) Where HEE exercises the power under subsection (6), it must publish—
- (a) the amendments in question, and
  - (b) its reasons for directing them to be made.
- (9) HEE may give LETBs directions about—
- (a) what to include in their education and training plans;
  - (b) how to present them.
- (10) An LETB may perform the duty under subsection (1) by preparing two or more documents which, taken together, specify how it proposes to exercise its main function.

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VALID FROM 01/04/2015

### **107 Commissioning education and training**

- (1) Each LETB must for each financial year arrange for the provision of education and training in accordance with its education and training plan for that year.
- (2) Where HEE considers that it would be better for the arrangements for the provision of certain education and training to be made on a national basis, it—
  - (a) may arrange for the provision of that education and training accordingly, or
  - (b) may direct one or more LETBs to do so on its behalf.
- (3) Before exercising a power under subsection (2), HEE must involve LETBs in making its decision.
- (4) HEE must for each financial year allocate to each LETB the amount that HEE considers appropriate to enable the LETB to comply with this section.
- (5) In doing so, HEE must take into account any duty to which the LETB is subject under section 108(9) (requirement to make payments by reference to an approved tariff price or a price varied under a specified procedure).
- (6) An LETB may arrange for another person to help it to exercise the function under subsection (1) or (where it is directed to do so under subsection (2)(b)) the function under subsection (2)(a) (and such functions as are exercisable for the purposes of or in connection with the exercise of the function concerned).
- (7) Each LETB—
  - (a) must keep under review the quality of the education and training the provision of which it arranges, and
  - (b) must report its findings to such persons as it considers may be interested by them.
- (8) An LETB must produce such reports on the exercise of the function under subsection (1) (including on the quality of the education and training the provision of which it arranges) as HEE may require.

VALID FROM 01/04/2015

### *Tariffs*

### **108 Tariffs**

- (1) The Secretary of State may specify a tariff setting approved prices in respect of education and training.
- (2) The approved prices may be different for different descriptions of education and training (and may in particular be different for different areas).
- (3) A tariff specified under subsection (1) must be published.

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- (4) If a tariff is specified under subsection (1), the Secretary of State may also specify a procedure for varying the approved prices in particular cases or descriptions of cases.
- (5) If the Secretary of State does so, the procedure—
  - (a) must be published, and
  - (b) must require a price as varied under the procedure to be published.
- (6) A published tariff or variation procedure may be revised or revoked by the Secretary of State.
- (7) If a tariff or variation procedure is revised, the Secretary of State must publish it as revised.
- (8) If it is revoked, the Secretary of State must publish a statement to that effect.
- (9) Where a tariff sets an approved price for a particular description of education or training, payments made by an LETB or HEE in respect of the provision of that description of education or training must be made—
  - (a) by reference to the approved price, or
  - (b) where the approved price has been varied in accordance with a variation procedure that has effect in relation to it, by reference to the price as varied.

## CHAPTER 2

### HEALTH RESEARCH AUTHORITY

#### *Establishment*

#### **109 The Health Research Authority**

- (1) There is to be a body corporate called the Health Research Authority (referred to in this Act as “the HRA”).
- (2) Schedule 7 (which includes provision about the HRA's constitution, the exercise of its functions and its financial and reporting duties) has effect.
- (3) The Special Health Authority called the Health Research Authority is abolished; and, in consequence of that, the following are revoked—
  - (a) the Health Research Authority (Establishment and Constitution) Order 2011 (S.I. 2011/2323), and
  - (b) the Health Research Authority Regulations 2011 (S.I. 2011/2341).
- (4) The Secretary of State may by order provide for the transfer of property, rights and liabilities from that Special Health Authority to the HRA; for further provision about an order under this section, see section 118.

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### *General functions*

#### **110 The HRA's functions**

- (1) The main functions of the HRA are—
  - (a) functions relating to the co-ordination and standardisation of practice relating to the regulation of health and social care research (see section 111);
  - (b) functions relating to research ethics committees (see sections 112 to 115);
  - (c) functions as a member of the United Kingdom Ethics Committee Authority (see section 116 and the Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031));
  - (d) functions relating to approvals for processing confidential information relating to patients (see section 117 and the Health Service (Control of Patient Information) Regulations 2002 (S.I. 2002/1438)).
- (2) The main objective of the HRA in exercising its functions is—
  - (a) to protect participants and potential participants in health or social care research and the general public by encouraging research that is safe and ethical, and
  - (b) to promote the interests of those participants and potential participants and the general public by facilitating the conduct of research that is safe and ethical (including by promoting transparency in research).
- (3) Health research is research into matters relating to people's physical or mental health; but a reference to health research does not include a reference to anything authorised under the Animals (Scientific Procedures) Act 1986.
- (4) Social care research is research into matters relating to personal care or other practical assistance for individuals aged 18 or over who are in need of care or assistance because of age, physical or mental illness, disability, pregnancy, childbirth, dependence on alcohol or drugs or other similar circumstances; and “illness” has the meaning given by section 275(1) of the National Health Service Act 2006.
- (5) A reference to health or social care research does not include a reference to research into matters which are within the legislative competence of a devolved legislature.
- (6) A reference to research that is ethical is a reference to research that conforms to generally accepted ethical standards.
- (7) Promoting transparency in research includes promoting—
  - (a) the registration of research;
  - (b) the publication and dissemination of research findings and conclusions;
  - (c) the provision of access to data on which research findings or conclusions are based;
  - (d) the provision of information at the end of research to participants in the research;
  - (e) the provision of access to tissue used in research, for use in future research.

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- (8) The Secretary of State may by order amend subsection (1) in consequence of—
- (a) functions being given to the HRA,
  - (b) functions being taken away from the HRA, or
  - (c) changes to the description of functions that the HRA has for the time being.

VALID FROM 01/01/2015

*Regulatory practice*

**111 Co-ordinating and promoting regulatory practice etc.**

- (1) The HRA and each of the following must co-operate with each other in the exercise of their respective functions relating to health or social care research, with a view to co-ordinating and standardising practice relating to the regulation of such research—
- (a) the Secretary of State;
  - (b) the licensing authority for the purposes of the Medicines Act 1968;
  - (c) the Health and Social Care Information Centre;
  - (d) the Chief Medical Officer of the Department of Health;
  - (e) the Human Fertilisation and Embryology Authority;
  - (f) the Human Tissue Authority;
  - (g) the Care Quality Commission;
  - (h) the Administration of Radioactive Substances Advisory Committee;
  - (i) such person, or a person of such description, as regulations may specify.
- (2) In performing the duty under subsection (1), a person must have regard to the need—
- (a) to protect participants and potential participants in health or social care research and the general public by encouraging research that is safe and ethical, and
  - (b) to promote the interests of those participants and potential participants and the general public by facilitating the conduct of such research.
- (3) The HRA must promote the co-ordination and standardisation of practice in the United Kingdom relating to the regulation of health and social care research; and it must, in doing so, seek to ensure that such regulation is proportionate.
- (4) The HRA and each devolved authority must co-operate with each other in the exercise of their respective functions relating to the regulation of assessments of the ethics of health and social care research, with a view to co-ordinating and standardising practice in the United Kingdom relating to such regulation.
- (5) The HRA must—
- (a) keep under review matters relating to the ethics of health or social care research and matters relating to the regulation of such research, and
  - (b) provide the Secretary of State with such advice about the matters referred to in paragraph (a) as the Secretary of State requests.
- (6) The HRA must publish guidance on—

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- (a) principles of good practice in the management and conduct of health and social care research;
  - (b) requirements, whether imposed by enactments or otherwise, to which persons conducting health or social care research are subject.
- (7) A local authority (within the meaning of Part 1), an NHS trust established under section 25 of the National Health Service Act 2006 and an NHS foundation trust must each have regard to guidance under subsection (6).
- (8) The ways in which persons may co-operate with each other under subsection (1) or (4) include, for example, by sharing information.
- (9) Section 290 of the Health and Social Care Act 2012 (duties for health and social care authorities to co-operate), so far as applying to a person who is for the time being within subsection (1), does not apply to functions of that person relating to health or social care research.
- (10) Section 110(5) (exclusion of research into matters within devolved competence) does not apply to the reference in subsection (1) or (4) to health and social care research.

VALID FROM 01/01/2015

### *Research ethics committees*

#### **112 The HRA's policy on research ethics committees**

- (1) The HRA must ensure that research ethics committees it recognises or establishes under this Chapter provide an efficient and effective means of assessing the ethics of health and social care research.
- (2) A research ethics committee is a group of persons which assesses the ethics of research involving individuals; and the ways in which health or social care research might involve individuals include, for example—
- (a) by obtaining information from them;
  - (b) by obtaining bodily tissue or fluid from them;
  - (c) by using information, tissue or fluid obtained from them on a previous occasion;
  - (d) by requiring them to undergo a test or other process (including xenotransplantation).
- (3) For the purposes of subsection (1), the HRA—
- (a) must publish a document (called “the REC policy document”) which specifies the requirements which it expects research ethics committees it recognises or establishes under this Chapter to comply with, and
  - (b) must monitor their compliance with those requirements.
- (4) The HRA may do such other things in relation to research ethics committees it recognises or establishes under this Chapter as it considers appropriate; it may, for example—
- (a) co-ordinate their work;

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- (b) allocate work to them;
  - (c) develop and maintain training programmes designed to ensure that their members and staff can carry out their work effectively;
  - (d) provide them with advice and help (including help in the form of financial assistance).
- (5) The requirements in the REC policy document may, for example, relate to—
- (a) membership;
  - (b) proceedings;
  - (c) staff;
  - (d) accommodation and facilities;
  - (e) expenses;
  - (f) objectives and functions;
  - (g) accountability;
  - (h) procedures for challenging decisions.
- (6) The HRA must ensure that the requirements imposed on research ethics committees in the REC policy document do not conflict with the requirements imposed on them by the Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031).
- (7) Before publishing the REC policy document, the HRA must consult—
- (a) the devolved authorities, and
  - (b) such other persons as it considers appropriate.
- (8) The HRA may revise the REC policy document and, where it does so, it must publish the document as revised; subsection (7) applies to a revised policy document in so far as the HRA considers the revisions significant.
- (9) The HRA must indemnify the members of each research ethics committee it recognises or establishes under this Chapter against any liability to a third party for loss, damage or injury arising from the committee's exercise of its functions in assessing the ethics of health or social care research.

### **113 Approval of research**

- (1) The HRA must publish guidance about—
- (a) the cases in which, in its opinion, good practice requires a person proposing to conduct health or social care research that involves individuals to obtain the approval of a research ethics committee recognised or established by the HRA under this Chapter, and
  - (b) the cases in which an enactment requires a person proposing to conduct research of that kind to obtain that approval.
- (2) Before publishing guidance under subsection (1), the HRA must—
- (a) consult the devolved authorities and such other persons as the HRA considers appropriate, and
  - (b) obtain the approval of the Secretary of State.
- (3) The HRA may revise guidance under subsection (1) and, where it does so, it must publish the guidance as revised; subsection (2) applies to revised guidance in so far as the HRA considers the revisions significant.

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- (4) Schedule 8 (which amends various references to research ethics committees in secondary legislation) has effect.

#### **114 Recognition by the HRA**

- (1) The HRA may, on an application made by or on behalf of a group of persons, recognise the group as a research ethics committee which is capable of—
  - (a) approving research of the kind referred to in section 113(1), and
  - (b) giving such other approvals as enactments require.
- (2) The HRA may not recognise a group under this section unless it is satisfied that—
  - (a) the group will, if recognised, comply with the requirements set out in the REC policy document, and
  - (b) there is or will be a demand for such a group.
- (3) In deciding whether to recognise a group under this section, the HRA must have regard to whether the group is recognised as a research ethics committee by or on behalf of a devolved authority.
- (4) The HRA may do anything (including providing financial assistance) to help a group wishing to be recognised under this section to reach a position from which it should be able to make an application for recognition under this section that is likely to succeed.
- (5) The HRA may revoke a recognition under this section if it is satisfied that—
  - (a) the group to which the recognition applies is not complying with the requirements specified in the REC policy document,
  - (b) the group is not (or is not properly) carrying out its function of assessing the ethical aspects of research, or
  - (c) revocation is necessary or desirable for some other reason.
- (6) A group in existence immediately before the commencement of section 109, and established or recognised by or on behalf of the old Health Research Authority, or by or on behalf of the Secretary of State, as a research ethics committee which assesses health or social care research is to be regarded as recognised by the HRA under this section.
- (7) The reference in subsection (6) to the old Health Research Authority is a reference to the Special Health Authority called the Health Research Authority (and abolished by section 109).

#### **115 Establishment by the HRA**

- (1) The HRA may establish research ethics committees which have the following functions—
  - (a) approving research of the kind referred to in section 113(1);
  - (b) giving such other approvals as enactments require.
- (2) The HRA must ensure that a research ethics committee established under this section complies with the requirements set out in the REC policy document.
- (3) The HRA may abolish a research ethics committee established under this section.



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## **116 Membership of the United Kingdom Ethics Committee Authority**

In regulation 5 of the Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031) (United Kingdom Ethics Committee Authority)—

- (a) in paragraphs (1), (2) and (3), for “the Secretary of State for Health”, in each place it appears, substitute “ the Health Research Authority ”, and
- (b) in paragraph (2), for “the Secretary of State” substitute “ the Health Research Authority ”.

VALID FROM 01/01/2015

### *Patient information*

## **117 Approval for processing confidential patient information**

- (1) The Health Service (Control of Patient Information) Regulations 2002 (S.I. 2002/1438) are amended as follows.
- (2) In regulation 5 (the title to which becomes “ Approval for processing information ”)—
  - (a) the existing text becomes paragraph (1), and
  - (b) in sub-paragraph (a) of that paragraph, for “both the Secretary of State and a research ethics committee” substitute “ the Health Research Authority ”.
- (3) After paragraph (1) of that regulation insert—

“(2) The Health Research Authority may not give an approval under paragraph (1)(a) unless a research ethics committee has approved the medical research concerned.”
- (4) After paragraph (2) of that regulation insert—

“(3) The Health Research Authority shall put in place and operate a system for reviewing decisions it makes under paragraph (1)(a).”
- (5) In regulation 6 (registration requirements in relation to information), in paragraph (1)—
  - (a) before “the Secretary of State” insert “ the Health Research Authority or ”, and
  - (b) before “he” insert “ it or ”.
- (6) In paragraph (2)(d) of that regulation, before “the Secretary of State” insert “ the Health Research Authority or (as the case may be) ”.
- (7) In paragraph (3) of that regulation, for the words from the beginning to “in the register” substitute “ The Health Research Authority shall retain the particulars of each entry it records in the register, and the Secretary of State shall retain the particulars of each entry he records in the register, ”.
- (8) For paragraph (4) of that regulation substitute—

“(4) The Health Research Authority shall, in such manner and to such extent as it considers appropriate, publish entries it records in the register; and the

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Secretary of State shall, in such manner and to such extent as he considers appropriate, publish entries he records in the register.”

VALID FROM 01/10/2014

## CHAPTER 3

### CHAPTERS 1 AND 2: SUPPLEMENTARY

#### *Miscellaneous*

#### **118 Transfer orders**

- (1) An order under section 96 (establishment of Health Education England) or section 109 (establishment of the Health Research Authority) (a “transfer order”) may make provision for rights and liabilities relating to an individual's contract of employment.
- (2) A transfer order may, in particular, make provision the same as or similar to provision in the Transfer of Undertakings (Protection of Employment) Regulations 2006 (S.I. 2006/246).
- (3) A transfer order may provide for the transfer of property, rights or liabilities—
  - (a) whether or not they would otherwise be capable of being transferred;
  - (b) irrespective of any requirement for consent that would otherwise apply.
- (4) A transfer order may create rights, or impose liabilities, in relation to property, rights or liabilities transferred.
- (5) A transfer order may provide for things done by or in relation to the transferor for the purposes of or in connection with anything transferred to be—
  - (a) treated as done by or in relation to the transferee or its employees;
  - (b) continued by or in relation to the transferee or its employees.
- (6) A transfer order may in particular make provision about continuation of legal proceedings.

#### *General*

#### **119 Chapters 1 and 2: interpretation and supplementary provision**

- (1) For the purposes of Chapters 1 and 2, an expression in the first column of the following table is defined or otherwise explained by the provision of this Act specified in the second column.

<i>Expression</i>	<i>Provision</i>
Appointment criteria	Section 104
Commissioner of health services	Section 105

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Devolved authority	Section 126
Devolved legislature	Section 126
Direct or direction	Subsection (2) below
Enactment	Section 126
Financial year	Section 126
Health care workers	Section 97
Health research	Section 110
The health service	Section 126
Health services	Section 99
HEE	Section 96
The HRA	Section 109
LETB	Section 103
Social care research	Section 110

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- (2) A power under Chapter 1 or 2 to give a direction—
- (a) includes a power to vary or revoke the direction by a subsequent direction, and
  - (b) must be exercised by giving the direction in question in writing.
- (3) The amendments made by sections 116 and 117 and Schedule 8 to provisions of subordinate legislation do not affect the power to make further subordinate legislation amending or revoking the amended provisions.

## CHAPTER 4

### TRUST SPECIAL ADMINISTRATION

#### 120 Powers of administrator etc.

- (1) In section 65O of the National Health Service Act 2006 (Chapter 5A of Part 2: interpretation) (the existing text of which becomes subsection (1)) at the end insert—
- “(2) The references in this Chapter to taking action in relation to an NHS trust include a reference to taking action, including in relation to another NHS trust or an NHS foundation trust, which is necessary for and consequential on action taken in relation to that NHS trust.
- (3) The references in this Chapter to taking action in relation to an NHS foundation trust include a reference to taking action, including in relation to another NHS foundation trust or an NHS trust, which is necessary for and consequential on action taken in relation to that NHS foundation trust.”
- (2) In section 65F of that Act (administrator's draft report), in subsection (1), for “45 working days” substitute “ 65 working days ”.

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- (3) In subsection (5)(a) of that section, for “would achieve the objective set out in section 65DA(1)(a)” substitute “—
- (i) would achieve the objective set out in section 65DA(1)(a), and
  - (ii) would do so without harming essential services provided for the purposes of the NHS by any other NHS foundation trust or NHS trust that provides services under this Act to the commissioner.”.
- (4) After subsection (7) of that section insert—
- “(8) Where the administrator recommends taking action in relation to another NHS foundation trust or an NHS trust, the references in subsection (5) to a commissioner also include a reference to a person to which the other NHS foundation trust or the NHS trust provides services under this Act that would be affected by the action.
  - (9) A service provided by an NHS foundation trust or an NHS trust is an essential service for the purposes of subsection (5) if the person making the statement in question is satisfied that the criterion in section 65DA(3) is met.
  - (10) Section 65DA(4) applies to the person making the statement when that person is determining whether that criterion is met.”
- (5) In section 65G of that Act (consultation plan), in subsection (2), for “30 working days” substitute “ 40 working days ”.
- (6) In subsection (4)(a) of that section, for “would achieve the objective set out in section 65DA(1)(a)” substitute “—
- (i) would achieve the objective set out in section 65DA(1)(a), and
  - (ii) would do so without harming essential services provided for the purposes of the NHS by any other NHS foundation trust or NHS trust that provides services under this Act to the commissioner.”.
- (7) After subsection (6) of that section insert—
- “(7) Where the administrator recommends taking action in relation to another NHS foundation trust or an NHS trust, the references in subsection (4) to a commissioner also include a reference to a person to which the other NHS foundation trust or the NHS trust provides services under this Act that would be affected by the action.”
  - (8) A service provided by an NHS foundation trust or an NHS trust is an essential service for the purposes of subsection (4) if the person making the statement in question is satisfied that the criterion in section 65DA(3) is met.
  - (9) Section 65DA(4) applies to the person making the statement when that person is determining whether that criterion is met.”
- (8) In section 65H of that Act (consultation requirements), in subsection (4)—
- (a) after “trust special administrator must” insert “—
  - (a)”,
  - and

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- (b) at the end insert “, and
- (b) in the case of each affected trust, hold at least one meeting to seek responses from staff of the trust and from such persons as the trust special administrator may recognise as representing staff of the trust.”
- (9) In subsection (7) of that section, after paragraph (b) (but before paragraph (ba) inserted by section 85(10)(a) of this Act) insert—
- “(bza) any affected trust;
- (bzb) any person to which an affected trust provides goods or services under this Act that would be affected by the action recommended in the draft report;
- (bzc) any local authority in whose area the trust provides goods or services under this Act;
- (bzd) any local authority in whose area an affected trust provides goods or services under this Act;
- (bze) any Local Healthwatch organisation for the area of a local authority mentioned in paragraph (bzc) or (bzd);”.
- (10) In subsection (8) of that section, omit paragraph (e).
- (11) In subsection (9) of that section—
- (a) after “trust special administrator must” insert “—
- (a)”,
- (b) after “subsection (7)(b),” (but before the insertion made by section 85(10)(b) of this Act) insert “ (bzb), ”, and
- (c) at the end insert—
- “(b) hold at least one meeting to seek responses from representatives of each of the trusts from which the administrator must request a written response under subsection (7)(bza), and
- (c) hold at least one meeting to seek responses from representatives of each of the local authorities and Local Healthwatch organisations from which the administrator must request a written response under subsection (7)(bzc), (bzd) and (bze).”
- (12) After subsection (11) of that section, insert—
- “(11A) In this section, “affected trust” means—
- (a) where the trust in question is an NHS trust, another NHS trust, or an NHS foundation trust, which provides goods or services under this Act that would be affected by the action recommended in the draft report;
- (b) where the trust in question is an NHS foundation trust, another NHS foundation trust, or an NHS trust, which provides services under this Act that would be affected by the action recommended in the draft report.
- (11B) In this section, a reference to a local authority includes a reference to the council of a district only where the district is comprised in an area for which there is no county council.”

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(13) In subsection (12)(a) of that section, after “subsection (7)(b)”, insert “, (bzb), (bzc) and (bzd)”.

(14) In section 65N of that Act (guidance), after subsection (1) insert—

“(1A) It must, in so far as it applies to NHS trusts, include guidance about—

- (a) seeking the support of commissioners for an administrator's recommendation;
- (b) involving the Board in relation to finalising an administrator's report or draft report.”

(15) In section 13Q of that Act (public involvement and consultation by NHS Commissioning Board), at the end insert—

“(4) This section does not require the Board to make arrangements in relation to matters to which a trust special administrator's report or draft report under section 65F or 65I relates before the Secretary of State makes a decision under section 65K(1), is satisfied as mentioned in section 65KB(1) or 65KD(1) or makes a decision under section 65KD(9) (as the case may be).”

(16) In section 14Z2 of that Act (public involvement and consultation by clinical commissioning groups), at the end insert—

“(7) This section does not require a clinical commissioning group to make arrangements in relation to matters to which a trust special administrator's report or draft report under section 65F or 65I relates before the Secretary of State makes a decision under section 65K(1), is satisfied as mentioned in section 65KB(1) or 65KD(1) or makes a decision under section 65KD(9) (as the case may be).”

(17) In section 242 of that Act (public involvement and consultation by NHS trusts and foundation trusts), in subsection (6)—

- (a) for “65I, 65R or 65U” substitute “ or 65I ”, and
- (b) for the words from “the decision” to the end substitute “ the Secretary of State makes a decision under section 65K(1), is satisfied as mentioned in section 65KB(1) or 65KD(1) or makes a decision under section 65KD(9) (as the case may be). ”

(18) In Schedule 14 to the Health and Social Care Act 2012 (abolition of NHS trusts in England: consequential amendments)—

- (a) after paragraph 4 insert—

“4A  
In section 13Q(4) (public involvement and consultation by Board), omit “makes a decision under section 65K(1),”.

4B  
In section 14Z2 (public involvement and consultation by clinical commissioning groups), omit “makes a decision under section 65K(1),”.”

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- (b) in paragraph 15(4), in the new subsection (2A) to be inserted into section 65F of the National Health Service Act 2006, in paragraph (a), for “would achieve the objective set out in section 65DA(1)(a)” substitute “—
- (i) would achieve the objective set out in section 65DA(1)(a), and
  - (ii) would do so without harming essential services provided for the purposes of the NHS by any other NHS foundation trust that provides services under this Act to the commissioner,”
- (c) in paragraph 15(4), after the new subsection (2C) to be inserted into that section, insert—
- “(2D) Where the administrator recommends taking action in relation to another NHS foundation trust, the references in subsection (2A) to a commissioner also include a reference to a person to which the other NHS foundation trust provides services under this Act that would be affected by the action.
- (2E) A service provided by an NHS foundation trust is an essential service for the purposes of subsection (2A) if the person making the statement in question is satisfied that the criterion in section 65DA(3) is met.
- (2F) Section 65DA(4) applies to the person making the statement when that person is determining whether that criterion is met.”
- (d) in paragraph 15, after sub-paragraph (7) insert—
- “(8) Omit subsections (8) to (10).”
- (e) in paragraph 16 (the text of which becomes sub-paragraph (1)) at the end insert—
- “(2) In subsection (4)(a)(ii) of that section, omit “or NHS trust”.
- (3) In subsection (7) of that section, omit “or an NHS trust” and “or the NHS trust”.
- (4) In subsection (8) of that section, omit “or an NHS trust”.
- (f) in paragraph 17, in sub-paragraph (2)(a), for “paragraph (b)” substitute “paragraphs (b), (bzb), (bzc) and (bzd)”,
- (g) in that paragraph, after sub-paragraph (4) insert—
- “(4A) In subsection (11A)—
- (a) omit paragraph (a), and
  - (b) in paragraph (b), omit “where the trust in question is an NHS foundation trust,” and “; or an NHS trust.”.
- (h) in paragraph 24, after sub-paragraph (2) insert—
- “(2A) Omit subsection (1A).”
- (i) after that paragraph insert—
- “24A In section 65O (interpretation)—
- (a) omit subsection (2), and

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- (b) in subsection (3), omit “or an NHS trust”., and
- (j) in paragraph 35, omit the “and” preceding paragraph (d) and after that paragraph insert “, and
- (e) in subsection (6), omit “makes a decision under section 65K(1),”.



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