These notes refer to the Care Act 2014 (c.23) which received Royal Assent on 14 May 2014

CARE ACT 2014

EXPLANATORY NOTES

COMMENTARY ON SECTIONS

Part 3 - Health

Chapter 1 - Health Education England

Establishment

Section 96 – Health Education England

536. This section establishes Health Education England (HEE) as a non-departmental public body. HEE will be the national body responsible for the planning and delivery of education and training for the NHS and public health workforce. It will also be responsible for establishing Local Education and Training Boards (LETBs) which will be responsible for planning and commissioning education and training at a local level.

537. *Subsection (2)* gives effect to Schedule 5 which, amongst other things, makes provision for the constitution of HEE, the exercise of its functions and its financial and accounting obligations.

538. *Subsection (3)* abolishes the Special Health Authority called HEE, and *subsection (4)* makes provision for the Secretary of State to transfer from that Special Health Authority any property, rights and liabilities to HEE. Section 118 makes further provision on transfer orders.

Schedule 5 – Health Education England

Part 1 – Constitution

Membership

539. *Paragraph 1* set outs the requirements for the membership of the Board of HEE. It provides that the Board must consist of a chair and six other non-executive members appointed by the Secretary of State, and a chief executive and no more than four executive members appointed by the chair and other non-executive members. Non-executive members are not employees of HEE. The chief executive and executive appointments will be employees of HEE.

540. *Paragraph 2* specifies that the Board of HEE must include persons with clinical expertise of a type set out in regulations. Regulations may specify the number of executive and non-executive members which must have that clinical expertise. The regulations will set out the types of expertise that must be represented, for example a doctor, a nurse or a member of one of the other healthcare professions.

541. Paragraph 2 also makes provision that the non-executive members of HEE must include a person who will represent the interests of patients.

Non-executive members: terms of office

542. *Paragraph 3* makes provision about the terms of appointment and tenure of office of non-executive members of the Board of HEE. Sub-paragraph (2) provides that non-executive appointments will be for a maximum period of four years. Sub-paragraph (3) confirms that non-executive members can be reappointed after they have ceased to be a member or at the end of the four year term of office. Sub-paragraph (4) provides that persons appointed to non-executive roles may resign from office by giving notice to the Secretary of State. Sub-paragraph (5) gives the Secretary of State a power to remove any person from a non-executive appointment on the grounds of incapacity, misbehaviour, or failure to carry out their duties properly. Sub-paragraph (6) permits the Secretary of State to suspend a person from a non-executive role for any of the reasons set out in sub-paragraph (5).

Non-executive members: suspension from office

543. *Paragraphs 4 and 5* set out the procedural requirements to be complied with when the Secretary of State suspends a non-executive member of the Board of HEE, make provision for the Secretary of State to review the suspension and gives the Secretary of State power to appoint an interim chair. HEE will have no power to appoint an interim chair, but could choose to appoint a deputy chair (regardless of any suspension of the chair).

Non-executive members: pay

544. *Paragraph 6* requires HEE to pay to the non-executive members such remuneration as the Secretary of State may decide. Sub-paragraph (2) provides that the Secretary of State may also determine the allowances and gratuities that HEE must pay a person who is or has been a non-executive member.

Employees: terms of office

545. *Paragraph 7* gives HEE the power to appoint the chief executive, executive members and other employees on such terms as it decides. The appointment of the chief executive requires the consent of the Secretary of State.

Employees: pay

546. *Paragraph 8* provides that HEE must pay its employees such remuneration as it decides. HEE must also pay such pensions, allowances or gratuities as it may determine. In common with other arms-length bodies, HEE is required to obtain the approval of the Secretary of State to its policy on pay before making a decision on these matters.

Committees and sub-committees

547. *Paragraph 9* provides that HEE may appoint committees and sub-committees and pay remuneration and allowances to those members of a committee or sub-committee who are not employees of HEE. Any committees or sub-committees of the Special Health Authority called HEE will become part of HEE when it is established as a non-departmental public body and will be treated as appointed for the purposes of this paragraph.

Procedure

548. *Paragraph 10*(1) provides that HEE regulates its own procedure. Paragraph 10(2) confirms that the validity of any act of HEE, will not be affected by vacancies or any defects in appointments.

Seal and evidence

549. *Paragraph 11* makes provision in relation to HEE's seal.

Status of HEE

550. *Paragraph 12* states that HEE is not to be regarded as a servant or agent of the Crown and will not enjoy any status, privilege or immunity of the Crown. HEE's property will not be regarded as property of, or property held on behalf of, the Crown.

Part 2 – Functions

Exercise of functions

551. Sub-paragraph (1) of *paragraph 13* imposes a duty on HEE to exercise its functions effectively, efficiently and economically. Under sub-paragraph (2) HEE may arrange for any of its committees, sub-committees, or members or any other person to exercise any of its functions on its behalf, subject to sub-paragraph (5).

552. Under sub-paragraph (3) HEE may arrange for any person to assist it in the exercise of its functions.

553. Under sub-paragraph (4) HEE may provide payment for remuneration and allowances when it arranges for any other person to exercise or assist in the exercise of its functions.

554. Sub-paragraph (5) provides that HEE is not permitted to arrange for a committee which is not an LETB, sub-committee, members or any other person to exercise the functions which are exercisable by a LETB.

555. Under sub-paragraph (6) HEE has a power to involve health care workers, patients and their carers in decisions about the exercise of its functions. In this context, "carer" means an adult who provides or intends to provide care for another person.

556. Under sub-paragraph (7) HEE has a general power to do anything necessary or desirable for the purposes of or in connection with the exercise of its functions.

557. Sub-paragraph (8) amends section 247C of the National Health Service Act 2006 (the 2006 Act) to include HEE in the list of bodies that the Secretary of State has a duty to keep under review in the exercise of their health service functions. In line with other arms-length bodies, the purpose of this is to ensure that the Secretary of State is ultimately accountable for ensuring that HEE performs its health care functions effectively.

Help or advice for public authorities

558. *Paragraph 14* states that HEE may provide help or advice to another public authority on such terms as it decides. Public authority is defined in sub-paragraphs (3) and (4) as any person whose functions are functions of a public nature and excludes the Houses of Parliament or a person exercising functions in connection with proceedings in Parliament. Public authorities in the Channel Islands or the Isle of Man are included within this definition, but others outside the UK are not.

Co-operation

559. *Paragraph 15* requires HEE to co-operate with the Secretary of State in the exercise of his public health functions. Public health functions are defined in section 1H of the 2006 Act.

560. Sub-paragraph (2) amends section 72 of the 2006 Act so that HEE is treated as a NHS body for the purposes of that section. Section 72 requires NHS bodies to co-operate with each other in the exercise of their functions. This means that all NHS bodies, along with those bodies included within the definition of NHS bodies for the purpose of this

section such as the National Institute for Health and Care Excellence and the Health and Social Care Information Centre, will be required to co-operate with HEE in the exercise of their functions, and in turn HEE will be required to co-operate with them.

561. Sub-paragraph (3) requires HEE and the Care Quality Commission to co-operate with each other, and HEE and Monitor to co-operate with each other.

562. Sub-paragraph (4) gives the Secretary of State a power to specify in regulations other bodies with which HEE must co-operate, and bodies which must co-operate with HEE.

NHS contracts

563. *Paragraph 16* adds HEE to the list of bodies eligible to enter into NHS contracts under the 2006 Act.

Arrangements with devolved authorities

564. *Paragraph 17* gives HEE a power to exercise on behalf of a devolved authority any functions which are similar to HEE's functions. There are occasions where UK wide co-operation and activity is required to support education and training, for example in planning for the medical workforce. This will allow HEE to lead work of this nature on behalf of the devolved authorities in circumstances where all parties have agreed to this. Sub-paragraph (2) makes provision for HEE to receive payment from the devolved authorities for any costs incurred under such arrangements.

Failure to exercise functions

565. *Paragraph 18* empowers the Secretary of State to intervene to direct HEE in the delivery of its functions, where he considers HEE is failing, or has failed to exercise any of its functions properly, and that the failure is significant. A significant failure could include circumstances where there is evidence that public money is not being used effectively; there are concerns about the quality of education and training and these are not being adequately addressed; plans look likely to lead to a shortfall in an important part of the professional workforce; or there are concerns that education and training is impacting on patient safety.

566. Sub-paragraph (2) states that if HEE fails to act as directed by the Secretary of State, the Secretary of State, or another person on his behalf, may carry out HEE's functions.

567. Sub-paragraph (3) requires the Secretary of State to publish reasons for intervention where HEE is failing, or where HEE has failed to take the remedial action stipulated by Secretary of State.

Part 3 – Finance and Reports

568. *Paragraphs 19 to 23* set out how the Secretary of State will fund HEE. It also sets out the general financial duties of HEE, including restrictions on the use of resources.

Funding

569. *Paragraph 19* provides that the Secretary of State must pay HEE the amount allotted for meeting HEE's expenditure. Sub-paragraph (2) provides that an amount will be regarded as allotted once HEE is notified of the amount. The payment is subject to such conditions relating to records, certificates or otherwise as the Secretary of State requires.

570. Sub-paragraph (3) states that the Secretary of State is able to increase or decrease the allotted amount if HEE agrees to the change, there is a parliamentary general election, or the Secretary of State considers that there are exceptional circumstances which make an increase or a decrease necessary. Such exceptional circumstances might include a severe disease outbreak or unpredictable and substantial damage to infrastructure.

571. Sub-paragraph (4) provides that the Secretary of State may direct HEE in respect of HEE's payments to it in respect of charges or other amounts relating to the valuation and disposal of assets.

Financial duties: expenditure

572. Under *paragraph 20*, HEE will have an obligation to ensure that its total expenditure does not exceed the aggregate of the amount allotted to HEE by the Secretary of State for that year and any income derived from other sources. This is in effect an annual "cash limit" on the total amount of cash expenditure which may be incurred.

573. The income which counts for the purposes of this limit would include, for instance, funds received as a result of the power in paragraph 21 for HEE to generate its own income.

574. The Secretary of State has the power to determine by directions what will and what will not count as total expenditure for the purposes of sub-paragraph (1). Sub-paragraph (3) gives the Secretary of State a power to determine in directions the extent to which, and the circumstances in which, sums received by HEE under *paragraph 19* but not yet spent must be treated for the purposes of this section as part of total expenditure, and to which financial year's expenditure they must be attributed.

575. The Secretary of State also has a power to direct HEE to use banking facilities that he specifies in the Directions.

Financial duties: use of generated income

576. *Paragraph 21* provides that any income that HEE generates must be re-invested for education and training purposes.

Financial duties: controls on total resource use

577. *Paragraph 22* is concerned with HEE's annual resource allocation. Under this paragraph, the total use of capital resources and the total use of revenue resources by HEE in a financial year must not exceed amounts specified by the Secretary of State. HEE is placed under a duty to ensure that these total limits are not exceeded.

578. The resource allocations include not only HEE's expenditure in the form of cash spending (that is, the cash spending that should be accounted for in that financial year, in line with resource accounting standards), but also consumption of other resources and the reduction in value of assets belonging to HEE (paragraph 22(4)). For example, the reduction in value of a photocopier across the year, or the distribution of leaflets previously kept in storage would be counted as part of the resource allocation. This system of setting not only a cash limit on HEE's expenditure but also a limit on use of resources reflects the system for controlling government resources under the Government Resources and Accounts Act 2000.

579. Sub-paragraph (2) gives the Secretary of State a power to give directions that specify what descriptions of resources must be treated as capital or revenue resources, and the uses of resources that must, or must not, be taken into account, when determining whether HEE has remained within the resource allocations for a financial year.

580. As with the allotment, the Secretary of State may only vary the resource allocations within a financial year if certain conditions are met. These conditions are set out in sub paragraph (3) and are that if HEE agrees that the change is necessary, if there is a parliamentary general election, or if the Secretary of State considers that exceptional circumstances require a variation of the allocation.

Financial duties: additional controls on resource use

581. *Paragraph 23* enables the Secretary of State to specify additional limits within the total revenue resource limit on the maximum use of resources attributable to administrative matters by HEE (sub-paragraph (1)(c)). Sub-paragraph (2) provides that the matters relating to administration which count for the purposes of these limits may be set out in directions.

582. Under sub-paragraphs (1)(a) and (1)(b), the Secretary of State will also be able to set additional limits on total revenue or total capital resource use attributable to particular matters specified in directions. Sub-paragraph (3) requires that the Secretary of State may only impose such limits for the purpose of complying with limits imposed by HM Treasury. These limits relate to specific budgetary limits applied across all Government Departments on certain elements of spending. For example within the revenue Departmental Expenditure Limit, HM Treasury applies a ring-fence to spending on depreciation. HM Treasury applies controls on Annually Managed Expenditure under which there are limits on the creation of new provisions (charges for spending that is likely to happen in future years e.g. the economic cost of providing student loans over the full repayment period. The Department of Health would also apply a limit on the balance of spending not covered by the specific limits, again to provide consistency with the controls applied by HM Treasury. These types of spending will fall within the total resource limits but need to be separately controlled within them.

Losses and liabilities etc

583. *Paragraph 24* provides that HEE is included in the list of authorities covered by section 265 of the Public Health Act 1875. The effect of this is to protect members and officers of HEE from personal liability in certain circumstances.

584. Sub-paragraph (3) includes HEE in the list of bodies eligible to enter into schemes for meeting losses and liabilities as set out in section 71 of the National Health Service Act 2006.

Accounts

585. *Paragraph 25* requires HEE to keep proper accounts and proper records in relation to the accounts (with such content and in such form, and using such methods and principles to prepare the accounts, as the Secretary of State may direct with the approval of HM Treasury). The chief executive of HEE is to be the chief accounting officer.

Annual accounts

586. *Paragraph 26* requires HEE to prepare consolidated accounts annually in respect of each financial year. HEE's consolidated accounts must include the accounts of each LETB, any other committees of HEE, and HEE's activities.

587. Sub-paragraph (3) provides that HEE must submit the accounts to the Secretary of State and to the Comptroller and Auditor General within such period as is directed by the Secretary of State. The Comptroller and Auditor General must examine, certify and report on the accounts of HEE and lay copies of the accounts, along with a report of them, before Parliament.

Interim accounts

588. Additional provision is made in *paragraph 27* for the Secretary of State, with the approval of HM Treasury, to direct HEE to prepare interim accounts. The interim accounts must include the accounts of any committees, including the LETBs.

589. HEE must submit the interim accounts to the Secretary of State and, if the Secretary of State directs, to the Comptroller and Auditor General within such period as is directed by the Secretary of State. The Comptroller and Auditor General must examine the

interim accounts of HEE and if the Secretary of State directs, send a copy of the report to the Secretary of State, and lay copies of the accounts, along with a report of them, before Parliament.

Annual report

590. *Paragraph 28* requires HEE to prepare an annual report for each financial year about how it has exercised its functions. This assessment must include an assessment of HEE's achievement of the objectives and reflection of the priorities set by the Secretary of State under subsection (1) of section 100 and an assessment of its achievement of the outcomes set by the Secretary of State for the purposes of subsection (2) of section 100. HEE must provide this report as soon as possible after the end of the financial year.

591. HEE must send a copy of the report to the Secretary of State and lay a copy of the report before Parliament. HEE must also provide such other reports and information relating to the exercise of its functions as the Secretary of State requests.

Part 4 – Consequential amendments

592. This Part makes consequential amendments to the following acts to include references to HEE where relevant – the Public Records Act 1958, the Public Bodies (Admission to Meetings) Act 1960, the Parliamentary Commissioner Act 1967, the House of Commons Disqualification Act 1975, the Copyright, Designs and Patents Act 1988, the Freedom of Information Act 2000, and the Equality Act 2010.

National Functions

Section 97 – Planning education and training for healthcare workers etc.

593. The Secretary of State has a duty in section 1F of the National Health Service Act 2006 (the 2006 Act) to carry out his functions under prescribed enactments, including section 63 of the Health Services and Public Health Act 1968 and the 2006 Act, to secure an effective system for the planning and delivery of education and training to persons who are employed, or who are considering becoming employed, in an activity which involves or is connected with the provision of services as part of the health service in England. The duty applies in relation to people working in the NHS and public health system, and to trainee professionals at the start of their career, before they enter employment in the NHS and public health system. The Secretary of State's duty was introduced in the Health and Social Care Act 2012.

594. Section 63 of the Health Services and Public Health Act 1968 gives the Secretary of State a power to provide, either directly or by entering into arrangements with others, education and training to persons specified in that section, which include all NHS and public health workers. Section 258 of the 2006 Act imposes a duty on the Secretary of State to make available facilities required by universities for clinical teaching and research connected with clinical medicine or clinical dentistry.

595. *Subsection (1)* delegates to HEE the Secretary of State's duty under section 1F, so far as it applies to its functions under section 63(1) and (5) of the Health Services and Public Health Act 1968, section 258(1) of the 2006 Act and any other of the enactments listed in section 1F(3) of that Act as regulations may specify. The delegation of the Secretary of State's duty gives HEE powers to take on responsibility for a wide range of matters relating to education and training, for example relating to workforce planning, the commissioning of education and training and the quality assurance and management of education and training provision. This power will also enable HEE to take on responsibility at a national level for continuing professional and personal development (CPD) provision, for example coordinating and leading CPD activities and investing funds in CPD.

596. *Subsection (2)* gives the Secretary of State a power by regulations to specify other functions of the Secretary of State to which section 1F(1) of the 2006 Act will apply, and to require HEE to carry out the resulting duty.

597. *Subsection (3)* gives the Secretary of State a power to specify that the duty in section 1F of the 2006 Act may be applied to persons of a specified description.

598. The 2006 Act places a duty on providers of NHS services, the National Health Service Commissioning Board (known as NHS England) and clinical commissioning groups to promote education and training to assist the Secretary of State in the discharge of his duty in section 1F. These duties are amended by *subsection (4)* to require co-operation with HEE to assist HEE, in addition to the Secretary of State, in the discharge of the section 1F duty.

599. *Subsection (5)* gives the Secretary of State power to make regulations to specify further functions for HEE relating to education and training.

600. *Subsection (6)* gives HEE a power to carry out other activities related to education and training, with the consent of the Secretary of State.

601. Section 63(6)(b) of the Health Services and Public Health Act 1968 gives the Secretary of State a power to pay travelling and other allowances to persons who are undertaking education and training under that section. *Subsection (7)* amends section 63(6) of that Act to give the Secretary of State a power to make such other payments as the Secretary of State considers appropriate and for payments to be made subject to such terms and conditions as the Secretary of State decides. The Secretary of State's power to make such payment means that provisions can be made about suspension or termination of payments, and overpayments could be required to be repaid.

602. *Subsection (8)* provides that the power of the Secretary of State under section 63(6) of the 1968 Act 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.

Section 98 – Ensuring sufficient skilled health care workers for the health service

603. This section places a duty on HEE to ensure that there is a sufficient number of healthcare workers with the skills and training to provide health services in England. For example, HEE will need to ensure that sufficient nurses are trained nationally to meet anticipated demand for future NHS service provision.

604. HEE has direct control over the investment in education and training for health professionals funded through the education and training budget. This budget totalled approximately £4.9 billion in 2013/14 and is invested in a wide range of undergraduate programmes, post registration and postgraduate training programmes and in NHS student support arrangements. Where necessary, HEE will work closely with other bodies to influence investment. For example, HEE will work with the Higher Education Funding Council for England, and universities across England who deliver healthcare related training programmes, to ensure that their funding is invested in the right areas and suitable training opportunities are available in the right places and in the right numbers.

605. *Subsection (2)* gives the Secretary of State the power to specify in regulations in relation to which healthcare workers the duty to ensure sufficient skilled workers should apply.

Section 99 – Quality improvement in education and training, etc.

606. *Subsection (1)* provides that HEE must exercise its functions with a view to securing continuous improvement in the quality of education and training provided to healthcare workers and in the quality of NHS services. The professional regulators such as the General Medical Council set the standards for health professionals to be registered to practise in the UK. In commissioning education and training, HEE and the LETBs

must build on these standards and will work with education providers to ensure that the provision of education and training continually improves in quality and delivers health professionals who are fit for purpose and meet the needs of employers in the NHS and their patients and service users.

607. *Subsection (2)* provides that HEE must, in exercising its functions, promote research into the activities listed in section 63(2) of the Health Services and Public Health Act 1968, such as primary dental or medical services, in so far as they are relevant to HEE's functions. HEE may do this by, for example, working closely with organisations such as the Academic Health Science Centres and Academic Health Science Networks. HEE must also promote the use of evidence obtained from this research.

608. *Subsections (3) and (4)* require HEE to have regard to the NHS Constitution and promote the NHS Constitution in carrying out its functions.

Section 100 – Objectives, priorities and outcomes

609. *Subsection (1)* stipulates that the Secretary of State must publish a document which specifies the objectives and priorities for HEE in relation to the education and training to be provided to health care workers. This document will be commonly referred to as HEE's mandate. It will be reviewed annually, before the beginning of each financial year, and republished if changes are made.

610. *Subsection (2)* stipulates that the Secretary of State will publish a document that sets the outcomes for HEE to achieve having regard to its objectives and priorities. The document will be known as the Education Outcomes Framework and will include outcomes applicable to other organisations in the health and public health system. It will be supported by a range of measures so that the system can demonstrate at all levels education quality outcomes as they impact on patient experience, care and safety.

611. *Subsection (3)* permits the Secretary of State to revise HEE's mandate and the Education Outcomes Framework and also provides that it must be republished if it is revised.

612. *Subsection (4)* requires HEE to publish a document which specifies the priorities, objectives and outcomes it expects to achieve; these priorities, objectives and outcomes must be consistent with those set by the Secretary of State at subsections (1) and (2) above. The document must also include guidance to LETBs about how they should carry out their commissioning functions. HEE is required to review the document annually and republish it if it is amended. This document will be developed in consultation with the NHS Commissioning Board (known as NHS England) and Public Health England. It will underpin the relationship and resource allocation arrangements between HEE and the LETBs. It will set out the medium to long term context for the development of the NHS and public health workforce, and will provide the framework within which the LETBs will develop their education and training plans. *Subsection (5)* provides that in producing the document, HEE must have regard to longer term objectives relating to workforce planning and education and training provision. HEE's duty under subsection (4) can be met by publishing two or more documents which taken together comply with its obligations.

613. *Subsection (8)* requires HEE to review the document annually and if it revises it then it must republish the revised document.

Section 101 – Sections 98 and 100: matters to which HEE must have regard

614. This section specifies matters that HEE must have regard to when exercising its duties under sections 98(1) (ensuring sufficient skilled workers) and 100(4) (setting objectives, priorities and outcomes for education and training).

Section 102 – Advice

615. This section stipulates that HEE must make arrangements for obtaining advice from persons who are involved in, or have an interest in, the provision of education and training. The education and training landscape is multi-faceted, and many organisations have an interest in the development of health professionals, ranging from local employers in the NHS through to national organisations such as the professional regulators like the General Medical Council and professional bodies such as the medical Royal Colleges.

616. *Subsections (2) and (3)* stipulate that HEE must ensure it receives representations from specified groups. These groups include providers of NHS services, patients and their carers, the NHS and public health workforce or the trades unions who represent them and, professional regulators such as the Health and Care Professions Council. It also includes the range of bodies involved in the development and provision of education and training such as the medical Royal Colleges who support the development of curricula and the bodies involved in the delivery of further and higher education such as colleges and universities.

617. *Subsection (4)* requires HEE to advise the Secretary of State on any matters relating to its functions as the Secretary of State requests. The Secretary of State may specify in his request how and when the advice is to be provided.

Local functions

Section 103 – Local Education and Training Boards

618. This section provides for HEE's appointment of committees, known as Local Education and Training Boards (LETBs), to exercise HEE's functions on its behalf in so far as they are exercisable in respect of the local area. LETBs will plan and commission education and training and quality assure the education and training that has been commissioned for their areas. The LETB, as a committee of HEE, will work within the national framework set by HEE, but within that will address local priorities for education and training and be a forum for local workforce development in the NHS and public health system.

619. *Subsection (3)* confirms that the LETB should represent the interests of all providers of NHS and public health services in the area of the LETB. It is important that the LETB acts on behalf of all providers, for example, across primary care, secondary care and the public health system.

620. *Subsection (4)* ensures that the duties imposed on HEE by section 99 (1), (2) and (4) (quality improvement in education and training etc.) also apply to LETBs.

621. *Subsection (5)* provides that LETBs may co-operate with each other and two or more LETBs may exercise their functions jointly. LETBs may also be required to work closely together on specific elements of workforce planning or education provision, for example, where a healthcare provider has a presence in two or more LETBs.

622. *Subsection (6)* permits HEE to attend any LETB meetings about a matter of concern to HEE. This may be required where HEE has serious concerns about delivery of national workforce priorities, objectives and outcomes.

Section 104 – LETBs: appointment etc.

623. This section deals with the process by which HEE appoints LETBs. LETBs will be supported by operational staff who will be employed by HEE. These will include staff from the former Strategic Health Authorities and postgraduate medical and dental deaneries.

624. HEE will appoint LETBs, where a group of persons, which must include local healthcare providers for the area, persons who have clinical experience of a type specified in regulations and a person who will represent the interests of patients, come together and fulfil the requirements of the appointment criteria. HEE will set appointment criteria will be contained in a document that will primarily assess potential LETB's potential to carry out HEE's functions at a local level. They will assess the LETBs capacity and capability to carry out those functions, their ability to secure financial control and the proposed local governance arrangements. Schedule 6 makes further detailed provision about the area of LETBs, the appointment criteria and the exercise of HEE's functions.

625. HEE will assess potential LETB applicants and there will be three possible outcomes from the application process. Firstly, as set out in *subsection (1)* the applicants may meet all the criteria set by HEE and HEE is therefore satisfied that the LETB is capable of taking on all functions delegated to it. In this case the LETB will be appointed without any further conditions. Secondly, as set out in *subsection (2)* the applicants may meet some of the criteria set by HEE and HEE is satisfied that they are capable of taking on some, but not all of the functions delegated to them. In this case, the LETB will be appointed with conditions attached to their appointment. The third outcome is that the applicants meet some of the criteria but not all, and HEE is not satisfied that they can take on functions delegated to them, or that they do not meet any of the criteria. In this case, the LETB will not be appointed. In such circumstances HEE may, under *subsection (8)*, appoint its own employees as members of the LETB to take on responsibility for the education and training functions in that area until an application meets sufficient criteria.

626. *Subsections (3)* to (8) provide more detail on eligibility for LETB membership and the required composition of its membership. Subsection (3) sets out types of person who must be represented on a LETB. *Subsection (4)* specifies that regulations may set out the required numbers of persons with clinical expertise. *Subsection (5)* confirms that persons involved in the provision of education and training may also be members of a LETB and subsection (5)(b) allows HEE to specify other persons who are eligible to be appointed. *Subsection (6)* confirms that non-executive and executive members of HEE are not eligible for membership. *Subsection (7)* confirms that the majority of the members of the LETB must be drawn from providers of NHS and public health services in the LETB geographical area. This is important. Whilst LETBs will rightly include other partners as members, for example, from the education sector or commissioning organisations, their primary purpose is to plan and commission on behalf of local healthcare providers.

627. *Subsection (9)* requires HEE to appoint the chair of the LETB. The chair may not be a provider of NHS or public health services in the LETB's geographical area or a representative from a further or higher education institution in the LETB's geographical area.

628. *Subsection (10)* requires HEE to notify applicants in writing of the outcome of its decision, and any reasons for rejection. HEE will then publish the decision as set out in *subsection (11)*.

629. *Subsection (12)* provides that the members of the LETB must not use information obtained in that capacity for any other purposes.

630. *Subsection (13)* gives the Secretary of State a regulation making power to make further provision on the appointment of members of the LETB, the removal by HEE of members of a LETB and the suspension by HEE of members of a LETB.

Schedule 6 – Local Education and Training Boards

The area for which a LETB is appointed

631. *Paragraph 1* makes provision for the geographical area covered by the LETB. Sub-paragraph (1) requires HEE to ensure that the areas covered by all LETBs together cover the whole of England and do not overlap or coincide geographically.

632. Sub-paragraph (2) gives HEE a power to vary the area of a LETB. This may be required if there are changes in the area of neighbouring LETBs which lead to part of England being unrepresented by a LETB. HEE must also keep an up to date record of the geographical areas and publish that record.

Assessment of whether the members of LETBs meet the appointment criteria

633. *Paragraph 2* requires HEE to continue to assess LETBs to ensure they are compliant with the appointment criteria set by HEE. If a LETB in question is not meeting the criteria HEE must assess whether it is still able to exercise its functions. HEE will undertake such an assessment whenever it considers this appropriate. Sub-paragraph (2) requires HEE to notify the LETB of the outcome of the assessment and where HEE is not satisfied that it meets the appointment criteria HEE is required to give the reasons for this and publish these.

634. Sub-paragraph (3) provides that where a LETB is continuing to meet some but not all appointment criteria and HEE determines that it can still exercise its functions, HEE may impose conditions on the LETB relating to its operation.

635. Sub-paragraph (4) stipulates that where a LETB fails to meet sufficient appointment criteria to enable it to exercise its functions, HEE may do one or more of the following: appoint new members of the LETB; exercise the functions on behalf of the LETB; arrange for another LETB to take responsibility for the area.

636. Sub-paragraph (5) requires HEE to notify the LETB of the conditions it proposes to impose or action it proposes to take, and the reasons for doing so, before it may impose the conditions at sub-paragraph (3) or take actions described under sub-paragraph (4).

637. Sub-paragraph (6) requires HEE to publish the details of these conditions and the reasons for imposing them or taking that action.

638. Sub-paragraph (7) requires HEE to obtain the approval of a LETB before asking it to take on another LETB's functions as described in sub-paragraph (4)(c).

639. Sub-paragraph (8) provides that 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 the provider complies with requirements mentioned in sub-paragraphs (8)(a) and (b). Sub-paragraph (8)(a) states that providers must co-operate with any LETB which represents that provider because it has been appointed by HEE to represent it by virtue of sub-paragraph (4)(c). This obliges providers to co-operate with any LETB that represents both its interests and the interests of providers from a different geographical area that the LETB originally represented before it was appointed to additionally represent the interests of another LETB. Sub-paragraph (8)(b) states that providers must provide LETBs with such information as they may request.

640. Sub-paragraph (9) allows the Secretary of State to make regulations specifying other circumstances where HEE may intervene in the operation of the LETB.

Publication and review of the appointment criteria

641. Sub-paragraph (1) requires HEE to publish the appointment criteria that persons applying to be appointed as a LETB must meet. HEE is required to obtain the approval

of the Secretary of State before publishing this criteria. Sub-paragraph (2) requires HEE to keep the appointment criteria under review and make any necessary revisions. HEE is required to obtain the approval of the Secretary of State for any revisions that HEE considers significant.

Exercise of functions

642. *Paragraph 4* enables the Secretary of State, through regulations, to give the LETBs additional functions relating to education and training and impose requirements about how those functions should be exercised.

643. Sub-paragraph (2) allows a LETB to do anything which it considers necessary or desirable to enable it to carry out its functions.

644. Sub-paragraph (3) provides that where HEE considers that a LETB is failing to exercise one or more of its functions, or there is a significant risk that it may do so, HEE must direct the LETB on the exercise of such functions.

645. Sub-paragraph (4) stipulates that where a LETB fails to comply with the direction under sub-paragraph (3), HEE may intervene as described under paragraph 2(4) of this Schedule, which means that HEE may appoint new members of the LETB, exercise functions on behalf of the LETB, or arrange for another LETB to represent providers of services in the area.

Section 105 – LETBs: co-operation by providers of health services

646. *Subsection (1)* provides that regulations must require specified commissioners of health services to include in the arrangements under the National Health Service Act 2006 (the 2006 Act) for the provision of such services terms to ensure that the provider complies with requirements imposed under paragraphs (a), (b) and (c). Paragraph (a) states that providers must co-operate with any LETB in which it provides services. Paragraph (b) requires providers to provide LETBs with such information as they may request and paragraph (c) requires providers to comply with other obligations that may be specified. The regulations will seek to ensure that providers of NHS and public health services co-operate with the LETB in their area to support the planning, commissioning and provision of education and training. This may include the provision of workforce information to support such activities. Such regulations will support the duty imposed on commissioners by section 1F(2) of the 2006 Act.

647. *Subsection (3)* provides that the regulations may specify matters that the LETB must have regard to when considering the reasonableness of requesting a provider to cooperate with it, or to provide it with information.

Section 106 – Education and training plans

648. *Subsection (1)* requires LETBs to publish an education and training plan for each financial year. The education and training plan will set out, amongst other matters, the LETB's proposed investment in their current and future workforce. *Subsection (2)* makes provision for the content of the education and training plan. In developing their plans, the LETB must have regard to national objectives, priorities and outcomes set by the Secretary of State and HEE (under section 100), alongside the local priorities of the NHS and public health providers represented by the LETB.

649. *Subsection (3)* lists matters that a LETB must have regard to in the preparation of the plan.

650. *Subsection (4)* places a duty on the LETB to involve the providers it represents in the preparation of its education and training plans, along with commissioners of health services, Health and Wellbeing Boards and such other organisations that either it or HEE considers appropriate. It is important that education and training plans are informed by the local needs of the health and public health system.

651. *Subsection (5)* requires the LETB to submit its education and training plan to HEE for approval prior to publication. *Subsection (6)* enables HEE to direct LETBs to amend their education and training plans prior to approval. By operation of *subsection (7)*, in the case of LETBs which meet all appointment criteria, HEE's power is restricted to amendments that HEE considers necessary to ensure that the LETB will achieve the outcomes set by HEE under section 100(4)(b). This is intended to respect the autonomy of the LETB and therefore restricts any amendments to issues linked to nationally agreed priorities, objectives and outcomes. HEE must publish the amendments and the reasons for making them as described in *subsection (8*).

Section 107 – Commissioning education and training

652. This section requires each LETB to commission education and training activity that will support their plans for that year. HEE has a duty to allocate appropriate funding to each LETB in order to commission the necessary education and training activity.

653. There may be some circumstances where it is advantageous to have nationally co-ordinated provision of education and training, rather than leaving it to the discretion of LETBs. For example, some professions and medical specialties may require only very small numbers to be commissioned across England, so national level commissioning may be more appropriate. In such cases, *subsection (2)* gives HEE a power to make arrangements itself for the provision of education and training, or to direct a lead LETB to do so on behalf of itself (but the latter is subject to consultation with the LETB in question (*subsection (3)*).

654. *Subsection (4)* requires HEE to allocate to the LETB the resources that are required to deliver its education and training plan for that year.

655. *Subsection (5)* requires HEE to take account of any requirements placed on the LETB by section 108 – which requires an LETB to make payments by reference to an approved tariff price or price varied under a specified procedure – when making such an allocation.

656. *Subsection (6)* allows the LETB to arrange for another person to assist in the exercise of its commissioning functions.

657. *Subsection (7)* places a duty on LETBs to keep under review the quality of the education and training provision that it commissions, and imposes a duty on them to report its findings to such bodies that the LETB considers may be interested. This could include, for example, the relevant professional regulatory body.

658. *Subsection (8)* requires the LETB to produce such reports on the commissioning of education and training as HEE may require.

Tariffs

Section 108 – Tariffs

659. This section establishes a tariff-based system for funding clinical education and training – whereby providers receive the same payment for the same activity. This will enable a national approach to the funding of clinical placements, and provides for equality of treatment between different providers. The Secretary of State will set the tariff price.

660. One of the functions of HEE is to determine the way in which education and training activities are grouped together for the purposes of payment. *Subsection (2)* recognises that different tariffs will need to be set by the Secretary of State, depending on the groups developed by HEE.

661. *Subsection (4)* allows the Secretary of State to specify a procedure for making variations to a published tariff. This could either be a variation to the price of the tariff itself, or

a variation to the price being paid to a particular provider (or group of providers) on a case-by-case basis.

662. *Subsection (6)* allows the Secretary of State to revise or revoke any such variations. It also allows the Secretary of State to make any revisions or revocations to the tariff itself.

663. *Subsection (9)*(a) stipulates that where a tariff has been published by the Secretary of State, HEE – through their LETBs – will be required to make payments to providers at the published tariff price. Subsection (9)(b) confirms that – where there has been a variation to an approved price – that this new price should be used by HEE.

Chapter 2 – Health Research Authority

Establishment

Section 109 – The Health Research Authority

664. This section establishes a new body to be known as the Health Research Authority (HRA). The HRA is to have functions relating to health and social care research which are conferred in other sections in this chapter.

665. The HRA is to replace the Special Health Authority (SpHA) also known as the Health Research Authority and take on its functions, which include those relating to reviewing the ethics of research proposals in England. Like the SpHA, the HRA will have the objective of protecting and promoting the interests of actual and potential participants in health and social care research and the general public by facilitating and promoting high quality research that is safe and ethical. *Subsection (3)* abolishes the SpHA and the relevant instruments establishing it and conferring functions on it. *Subsection (4)* makes provision for the Secretary of State to make an order to transfer the property, rights and liabilities from the SpHA to the HRA.

Schedule 7 –The Health Research Authority

666. This Schedule makes provision for the constitution and establishment of the HRA.

Part 1 – Constitution

667. *Paragraph 1* makes provision about the membership of the HRA. The Board will be made up of a chair, three or four non-executive members, a chief executive and two or three executive members.

668. *Paragraph 2* makes provision about the terms of appointment and tenure of office of non-executive members. Sub-paragraph (2) specifies that the maximum term for a non-executive is 4 years. Sub-paragraph (3) specifies that a person who ceases to be a non-executive member is eligible for re-appointment. Provision is made in sub-paragraph (4) to enable a non-executive member to resign at any time by giving notice to the Secretary of State, and sub-paragraphs (5) and (6) enable the Secretary of State to remove or suspend non-executive members from office on the grounds of incapacity, misbehaviour or failure to carry out his or her duties as a non-executive member.

669. *Paragraph 3* sets out the procedural requirements to be complied with where the Secretary of State suspends a non-executive member of the HRA under the power in paragraph 2(6).

670. *Paragraph 4* enables the Secretary of State to appoint a non-executive member as interim chair where the chair is suspended under paragraph 2(6), and sets out the conditions that apply to that appointment.

671. *Paragraph 5* requires the HRA to make payments to the non-executive members and the chair. The level of these payments would be determined by the Secretary of State.

672. *Paragraph 6* gives the HRA powers to appoint employees on such terms as it may determine. The appointment of the chief executive must be agreed by the Secretary of State.

673. *Paragraph 7* allows the HRA to decide the levels of pay, pensions or allowances it will make to its staff. In line with other arms-length bodies (for example, Monitor, Care Quality Commission, NHS Commissioning Board (known as NHS England) and, as covered by this Act, HEE), the HRA would be required to seek the approval of the Secretary of State to its policy on pay, pensions and allowances.

674. *Paragraph 8*makes provision about the appointment of committees and sub-committees by the HRA. Sub-paragraph (1)(a) and (b) requires the HRA to appoint a committee to advise the HRA and the Secretary of State in relation to their respective functions under the Health Service (Control of Patient Information) Regulations 2002. The advice to be given under sub-paragraphs (1)(a) and (1)(b) includes advice on applications to process confidential patient information for medical purposes to the HRA in the case of medical research and to the Secretary of State in other cases.

675. Sub-paragraph (1)(c) requires the committee to advise the Health and Social Care Information Centre. The committee would supply advice in connection with HSCIC's exercise of functions pursuant to further regulations under section 251 of the 2006 Act, and also in connection with any publication or other dissemination by HSCIC of information which identifies an individual or could potentially be used to identify an individual.

676. Sub-paragraph (3) requires the committee under sub-paragraph (1) to consist of persons independent of the HRA. Sub-paragraph (2) enables the HRA to appoint other committees and sub-committees. Committees appointed under paragraph 8 can include participants in research, potential participants and the public as well as any persons with particular expertise relevant to the committee's work, for example, nurses or social workers or any other person HRA considers appropriate. The HRA may pay members of its committees where they are not employees of the HRA.

677. *Paragraph 9* provides a power to set out in regulations the specific factors or matters to which the committee appointed by the HRA under paragraph 8(1) of Schedule 7 must have regard when advising on the exercise by:

- the HRA or the Secretary of State of functions under the Health Service (Control of Patient of Patient Information) Regulations 2002, or
- the HSCIC of functions pursuant to further regulations under section 251 of the 2006 Act or any publication or other dissemination by the HSCIC of information which identifies or could be used to identify an individual.

Such factors or matters might include the need to ensure processing must respect and promote patient privacy and that an applicant for access to such information has not breached confidentiality in the past.

678. *Paragraph 10* allows the HRA to regulate its own procedure. So for example, this power may enable the HRA to remove the risk of a conflict of interest by preventing executive members from being involved in determining their own pay. Sub-paragraph (2) provides that a vacancy amongst the members of the HRA or a defect in appointment of a member does not prevent the HRA from continuing to operate.

679. *Paragraph 11* makes provision in relation to the HRA's seal which would be used to show approval of official HRA documents.

680. *Paragraph 12* provides that the status of the HRA would be a non-departmental public body that is not part of the Crown, nor regarded as a servant or agent of the Crown.

Part 2 - Functions

681. *Paragraph 13* places a requirement on the HRA to exercise its functions effectively, efficiently and economically. Provision is made to enable the HRA to arrange for any person to exercise on its behalf, or assist with the exercise of its functions and to make payments to them. Sub-paragraph (5) gives the HRA a general power to do anything which appears to it to be necessary or desirable for the purpose of, or in connection with the exercise of its functions.

682. *Paragraph 14*(1) makes provision for the HRA to provide help or advice to another public authority (as defined in sub-paragraphs (3) and (4)) for the purpose of the exercise of functions by that public authority to meet its objectives. By way of example, it is envisaged that this power could be used to enable HRA to advise and assist the Human Fertilisation and Embryology Authority in relation to applications to process information under the Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010 (S.I. 2010/995). Sub-paragraph (2) makes provision for the HRA to determine the terms under which it provides the help or advice in sub-paragraph (1), including rates of pay and allowances.

683. *Paragraph 15* enables Scottish Ministers, Welsh Ministers, or the Department of Health, Social Services and Public Safety in Northern Ireland to arrange for the HRA to exercise certain functions. These are those functions which relate to health or social care research and correspond to a function of the HRA, or to provide services or facilities to them in connection with the exercise of such functions. Sub-paragraph (2) makes express provision to enable the parties to agree for the HRA to receive payments to recoup its costs.

684. If the Secretary of State considers that the HRA is failing or has failed to exercise its functions, and the failure is significant, *paragraph 16*(1) would give the Secretary of State the power to direct the HRA to perform its functions. If the HRA fails to comply with the direction made under sub-paragraph (1), sub-paragraph (2) would enable the Secretary of State to exercise the functions specified in the direction, or make arrangements for another person to exercise those functions on his behalf. Where the Secretary of State exercises the power under sub-paragraph (1) or (2), he must publish the reasons for doing so

Part 3 – Finance and reports

685. *Paragraph 17* makes provision for the Secretary of State, with the consent of the Treasury, to make payments to the HRA. The payments could be made at any time and have any conditions attached to them which the Secretary of State considers appropriate.

686. *Paragraph 18* gives the Secretary of State the power to make regulations requiring a fee to be paid to the HRA for specified functions. Any regulations made under this section would be subject to the affirmative parliamentary procedure. Any fees prescribed under this section, as determined by the HRA, would need to take account of the cost of the functions involved and must be approved by the Secretary of State.

687. Paragraph 18(7) applies existing legislation so that the members and staff of HRA are protected from personal liability whilst carrying out work on behalf of HRA. Paragraph 17(9) amends section 71 of the National Health Service Act 2006 to add the HRA to the list of bodies that may join a scheme established by the Secretary of State for the purpose of meeting expenses arising from any loss, damage or injury incurred by members, to their property and liabilities, and to third parties for loss damage or injury arising out of carrying out the functions of the bodies.

688. *Paragraph 19*(1) requires the HRA to keep accounts and prepare annual accounts for each financial year in a form to be determined by the Secretary of State, and which must be audited by the Comptroller and Auditor General.

689. *Paragraph 20* requires the HRA to prepare an annual report on the activities it has undertaken during the previous financial year and the activities it proposes to undertake during the current financial year. The report must include information about health and social care research which has taken place during the year as well as setting out the steps the HRA has taken to fulfil its objectives under section 110(2). The HRA must lay a copy of the report before Parliament and send a copy to the Secretary of State. Paragraph 19(4) provides that the HRA must provide the Secretary of State with other reports and information relating to the exercise of its functions on request.

Part 4 – Consequential amendments

690. *Paragraphs 21 to 27* make amendments to other primary legislation so that the relevant provisions apply to the HRA. For example, paragraph 23 amends Part 2 of Schedule 1 to the House of Commons Disqualification Act 1975 to insert the HRA into the list of bodies whose members are disqualified from membership of the House of Commons.

General functions

Section 110 – The HRA's functions

691. *Subsection (1)* sets out the HRA's main functions. These functions relate to the co-ordination and standardisation of practice relating to the regulation of health and social care research, research ethics committees, membership of the United Kingdom Ethics Committee Authority under the Medicines for Human Use Clinical Trials) Regulations 2004 (Clinical Trials Regulations), and the process for approving the processing of confidential patient information for medical research. The functions are set out in detail in sections 109 to 115.

692. *Subsection (2)* sets out the main objective of the HRA when performing its functions to:

- protect participants and potential participants in health and social care research and the general public by encouraging safe and ethical research which conforms to generally accepted ethical standards as described in *subsection (6)*; and
- promote their interests by facilitating the conduct of research which is safe and ethical. This includes by promoting transparency in research. *Subsection (7)* lists some of the ways in which transparency in research can be promoted, for example, by promoting the publication and dissemination of research findings and conclusions.

693. Therefore, for example, in carrying out its duty to cooperate with other bodies that hold research related functions the HRA would need to act in a way that will ensure that people are protected through safe and ethical standards whilst also facilitating research. This might involve, for example, removing duplication and ensuring proportionate regulation.

694. *Subsection (3)* defines health research as research into matters relating to people's physical or mental health. The definition does not include health research involving animals that is regulated by the Animals (Scientific Procedures) Act 1986. *Subsection (4)* defines social care research as 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 for any of the reasons listed. The definitions of health research and social care research are not restricted to any particular professional group so, for example, they would include nurse-led research. The references to health or social care research in this chapter do not, except where otherwise stated, include research into matters which are within the legislative competence of the devolved legislature (the Scottish Parliament, the National Assembly for Wales or the Northern Ireland Assembly) (*subsection (5)*).

695. *Subsection (8)* provides a power to amend by order the list of functions in subsection (1) in consequence of functions being given to or taken away from the HRA or amended by other statutory enactments.

Regulatory practice

Section 111 – Co-ordinating and promoting regulatory practice etc.

696. *Subsection (1)* imposes an obligation on the HRA and the people and bodies listed to co-operate with each other. The aim of this subsection is to encourage co-ordination and standardisation of practice of such bodies and persons when carrying out functions relating to the regulation of health and social care research. *Subsection (2)* provides that when exercising the duty to co-operate the HRA and specified people and bodies must have regard to the need to protect participants in health and social care research and the general public by encouraging safe and ethical research as well as promoting the interests of those people by facilitating the conduct of such research.

697. For example, the Secretary of State has both a duty to promote research in relation to the health service under section 1D of the National Health Service Act 2006 (the 2006 Act) and a power under paragraph 13 of Schedule 1 to the 2006 Act to conduct, commission or assist the conduct of research into any matters relating to the causation, prevention, diagnosis or treatment of illness, and research into any other matters connected with a service provided under the 2006 Act. The Secretary of State currently relies on these provisions to establish the National Institute for Health Research (NIHR) which funds research and the infrastructure to support research. As part of this role, the NIHR seeks to promote and coordinate proportionate research management systems within the NHS. Subsection (1)(a) requires the Secretary of State to work cooperatively with the HRA in relation to functions such as that of the NIHR.

698. The references to the Secretary of State and the licensing authority in subsection (1)(a) and (b) ensure that functions carried out by the Medicines and Healthcare Products Regulatory Executive Agency fall within the duty to co-operate. The reference to the Chief Medical Officer in subsection (1)(d) ensures that the Chief Medical Officer's function of receiving abortion notifications under regulation 4(1) of the Abortion Regulations 1991 (made under section 2 of the Abortion Act 1967) is covered by the duty.

699. There is a power to add to the list of the HRA's co-operation partners by way of regulations under subsection (1)(i). This may be used to include bodies that have relevant health and social care research functions conferred upon them in the future.

700. *Subsection (3)* imposes a freestanding duty on the HRA only to promote the co-ordination and standardisation of practice in relation to the regulation of health and social care research giving it the lead role in removing duplication and streamlining the regulation of health and social care research across the regulatory system. This is in addition to the reciprocal duty on HRA and the other bodies listed in subsection (1) to co-operate with each other in this particular area insofar as their respective functions relate to the regulation of health and social care research. One way in which the HRA might meet this duty could be by continuing to run an integrated research application system (IRAS) currently administered by the HRA SpHA and by building on it to create a unified approvals process for research. The IRAS enables a researcher to enter information about their project into one application form which includes the information required for a number of different research approvals by different bodies.

701. *Subsection (4)* imposes an obligation on the HRA and the devolved authorities to co-operate with each other in the exercise of their functions where they relate to the regulation of assessments of the ethics of health and social care research, with a view to coordinating and standardising practice in the United Kingdom relating to the regulation of such research. Health and social care research in this context includes research that

relates to the functions exercisable by a devolved authority or which is within the legislative competence of the devolved legislature (*subsection (10)*).

702. *Subsection (5)* requires the HRA to undertake a horizon scanning function to keep under review matters relating to the ethics of health and social care research and to advise the Secretary of State about such matters if requested.

703. The Department of Health currently publishes the Research Governance Framework for Health and Social Care which sets out the broad principles for good research governance. *Subsection (6)* requires the HRA to publish guidance on principles of good practice in the conduct and management of health and social care research, and any requirements imposed upon researchers in legislation or by other sources.

704. Under *subsection (7)*, a local authority, an NHS trust in England and an NHS foundation trust must have regard to guidance published under subsection (6).

705. *Subsection (8)* makes express provision that co-operation under subsection (1) or (4) can include sharing information.

Research ethics committees

Section 112 – The HRA's policy on research ethics committees

706. This section states the general policy of the HRA in relation to research ethics committees (RECs) it recognises or establishes under sections 114 and 115. The HRA needs to ensure that RECs provide an efficient and effective means of assessing the ethics of health and social care research. *Subsection (4)* sets out ways in which the HRA may fulfil this function, such as co-ordinating and allocating work to RECs, and providing help and advice. The HRA may also develop and maintain a training programme to ensure that RECs' members and staff can carry out their work effectively. *Subsection (9)* requires the HRA to indemnify members of the RECs against certain risks that may be involved in the exercise of the committees' functions in assessing the ethics of health and social care research.

707. RECs are defined by *subsection (2)* as a group which assesses the ethics of research involving individuals and gives examples of how research may involve individuals, including obtaining information, tissue or fluid from them.

708. *Subsection (3)* requires the HRA to publish a REC policy document to set out the requirements that RECs recognised or established by the HRA would be expected to comply with and must monitor their compliance. These requirements are currently set out in the Governance arrangements for RECs (GAfREC) document published by the Department of Health. *Subsection (5)* lists the requirements that may be included in the REC policy document. *Subsection (6)* requires the HRA to ensure that the requirements in the REC policy document do not conflict with the requirements imposed on ethics committees under the Clinical Trials Regulations. The Clinical Trials Regulations establish a body called the United Kingdom Ethics Committee Authority (UKECA) which has the power to establish and recognise ethics committees for the purpose of approving clinical trials on investigational medicinal products for human use in the UK under the Clinical Trials Regulations. This subsection would enable a committee which is recognised or established by the HRA also to be able to meet the requirements for recognition by UKECA to ethically approve clinical trials of investigational medicines under the clinical trials regulations so as to avoid duplication. *Subsection (8)* allows the HRA to revise the document.

709. *Subsection (7)* requires the HRA to consult the devolved authorities and anyone else it considers appropriate on the content of the document before it is published. This also applies to any significant revision of the document made under subsection (8).

Section 113 – Approval of research

710. At present the Department of Health issues policy guidance on RECs (the GAfREC document) which sets out when the Department considers it is good practice or legislation requires them to seek approval of research by a REC, or where legislation requires the researcher to do so. *Subsection (1)* of this section requires the HRA to publish guidance setting out when it considers it good practice to seek approval of research by a REC.

711. *Subsection (2)* requires the HRA to consult the devolved authorities and other people it considers appropriate, and obtain approval of the Secretary of State before publishing guidance. Where the HRA revises its guidance, and it considers the revisions significant, it must consult and seek approval from the Secretary of State before publishing the revised guidance (*subsection (3)*).

712. *Subsection (4)* introduces Schedule 8, which contains amendments relating to references to RECs in secondary legislation.

Schedule 8 – Research ethics committees (RECs): amendments

713. Schedule 8 makes consequential amendments to secondary legislation where references are made to RECs. The amendments replace references to ethics committees recognised by the Secretary of State with reference to those established or recognised by the HRA. The amendments also standardise the definitions of RECs to bring them into line with the definition of a REC under section 112.

Section 114 – Recognition by the HRA

714. This section makes provision for the HRA, following an application by or on behalf of a group of people, to recognise that group as a REC for the purpose of approving research of a type specified by the HRA in the guidance issued under section 113(1) or for the purpose of approving research where this is required under other legislation.

715. Under *subsection (2)* the HRA would only be able to recognise a REC if it is satisfied that the REC meets the requirements of the REC policy document published by the HRA under section 112*(3)*, and that there is, or will be, a demand for such a group. *Subsection (3)* would require the HRA to take into consideration whether the group is already recognised as a REC by, or on behalf of, a devolved authority. *Subsection (4)* enables the HRA to do anything (including provide financial assistance) to help a group of people who want to be recognised to make an application which is likely to be successful. Therefore, for example the HRA may consider it appropriate to make a meeting room available to a REC in which they can conduct their business.

716. *Subsection (5)* gives the HRA the power to revoke recognition of a REC where it is satisfied that the recognised REC is not complying with the requirements of the REC policy document published by the HRA under section 112(3). Recognition may also be revoked if the HRA is satisfied that the group is not carrying out its function of assessing the ethical aspects of research, or is not doing so properly, or that the revocation is necessary or desirable for another reason.

717. Any group which was established or recognised by the SpHA Health Research Authority or by the Secretary of State as a REC, and which exists when the new provisions come into force would, under *subsection (6)*, receive automatic recognition by the HRA.

Section 115 – Establishment by the HRA

718. This section gives the HRA the power to establish RECs for the purpose of approving research of the type specified by the HRA in the guidance document issued under section 113(1), or giving such other approvals as are required. The HRA would be required, under *subsection (2)*, to ensure that any REC it establishes complies with the

requirements in the REC policy document. Therefore, for example, if the guidance sets out requirements for lay membership, the REC must comply. *Subsection (3)* provides that the HRA has the power to abolish a REC it has established under this section.

Section 116 – Membership of the United Kingdom Ethics Committee Authority

719. This section amends regulation 5 of the Clinical Trials Regulations which provides for the membership of the United Kingdom Ethics Committee Authority (UKECA) to replace the Secretary of State's membership with that of the HRA and makes other amendment consequential on this change.

Patient Information

Section 117 – Approval for processing confidential patient information

720. This section makes a number of amendments to the Health Service (Control of Patient Information) Regulations 2002 (S.I. 2002/1438) (the 2002 Regulations). These amendments transfer the Secretary of State's power to approve the processing of confidential patient information for research purposes to the HRA and change the way that the requirement for REC approval is expressed legally. These changes will retain the safeguards currently in place.

721. *Subsection (2)* amends regulation 5 of the 2002 Regulations to replace the requirement for approval from the Secretary of State and a REC for the processing of confidential patient information for the purpose of medical research, with a requirement for approval only from the Health Research Authority (new regulation 5(1)(a)). *Subsection (3)* inserts new sub-paragraph (2) into regulation 5 of the 2002 Regulations which provides that the HRA may not give approval under new paragraph 5(1)(a) unless a REC has approved the medical research concerned. This means that approval for processing confidential patient information for the purpose of medical research would require approval by the HRA as well as REC approval of the ethical aspects of the research concerned.

722. *Subsection (4)* inserts new sub-paragraph (3) into regulation 5 of the 2002 Regulations to require the HRA to put in place a system for reviewing decisions it makes in relation to the processing of patient information under sub-paragraph (1)(a).

723. *Subsections (5) to (8)* amend regulation 6 of the 2002 Regulations to require the HRA to record in a register details about any transfer of information which is approved under the regulations. Provision is also made to require the HRA to retain such information and to enable it to publish any entries in the register, as it considers appropriate.

Chapter 3 – Chapters 1 and 2: Supplementary

Miscellaneous

Section 118 – Transfer orders

724. Section 118 makes provision on transfer orders under section 96 (establishment of Health Education England) or section 109 (establishment of the Health Research Authority). Such an order may make provision for rights and liabilities relating to an individual's contract of employment.

725. In particular, it provides that, a transfer order may, amongst other matters, require that employees of the Special Health Authority are transferred to HEE or HRA as the case may be, under terms which are the same as or similar to those made by the Transfer of Undertakings (Protection of Employment) Regulations 2006 which provides certain protections of employment rights for transferred staff.

General

Section 119 – Part 3: interpretation and supplementary provision

726. This section contains interpretation provisions for Part 3.

Chapter 4 – Trust Special Administration

Section 120 – Powers of administrator etc.

727. This section further amends provisions relating to the functions of Trust Special Administrators (TSAs). Appointment of a TSA is one way in which action can be taken in exceptional circumstances to deal with NHS trusts and NHS foundation trusts which are operating unsustainably in their current form. On a TSA's appointment, an NHS trust's board of directors, and for an NHS foundation trust its council of governors also, is suspended. The TSA must produce a report stating the action the TSA recommends should be taken by the Secretary of State (in relation to NHS trusts) or Monitor (in relation to NHS foundation trusts).

728. The provisions for the Trust Special Administration regime were first introduced in the Health Act 2009, and provisions in the Health and Social Care Act 2012 amended them in relation to NHS foundation trusts. Although the arrangements for NHS trusts and NHS foundation trusts are similar, there are differences that reflect the greater autonomy of NHS foundation trusts. The Secretary of State appoints a TSA to an NHS trust, whilst Monitor appoints a TSA to an NHS foundation trust. The statutory objective of the trust special administration when a TSA is appointed to an NHS foundation trust is to ensure the continued provision of essential NHS services provided by that failing trust, whereas the Secretary of State sets the objective of the trust special administration at an NHS trust at the time of appointment of the TSA. The TSA of an NHS foundation trust is required by statute to seek the support of commissioners for their recommendations, whereas current expectations of a TSA of an NHS trust are set out in statutory Guidance. The final report on an NHS trust is submitted to the Secretary of State who decides what action to take, whilst the final report on an NHS foundation trust is submitted to Monitor which decides whether to accept the recommendations, with the Secretary of State having power to veto the recommendations if he is not satisfied, in accordance with various specified criteria.

729. This section amends the parts of the NHS Act 2006 and the Health and Social Care Act 2012, relating to the TSA's functions and special administration arrangements, to make six changes.

730. *Subsection (1)* provides that a TSA appointed to a failing NHS trust or NHS foundation trust has power to make recommendations, and Monitor/the Secretary of State has the power to take decisions, that go wider than the trust under administration. This includes where the action affects other NHS trusts and NHS foundation trusts, and action which is "necessary for and consequential on" action taken in relation to the failing trust. These powers are not to be applied retrospectively.

731. *Subsections (2)* and *(5)* will give the TSA more time to complete two stages in their work. Subsection (2) increases the time period for the TSA to produce the draft report from 45 to 65 working days. Subsection (5) increases the period for the TSA to carry out the statutory consultation from 30 to 40 working days. The Secretary of State and Monitor's powers to extend the statutory deadlines of the regime remain in place.

732. *Subsections (3), (4), (6)* and *(7)* amend the provisions relating to commissioner agreement to the recommendations of a TSA appointed to an NHS foundation trust, by requiring agreement to be sought from commissioners of other NHS trusts or NHS foundation trusts affected by the recommendations, in addition to commissioners of the trust under administration. This applies in relation to the TSA's draft report, under

subsections (3) and (4), and before any variation can be made to the draft report when producing the final report after the TSA's consultation, under subsections (6) and (7).

733. Each commissioner must agree that the objective of the TSA has been achieved by the recommendations. In addition, each commissioner who commissions services from other trusts which the TSA's recommendations affect, must also agree that the recommendations do not harm essential services at those other trusts which they commission. Essential services are defined at subsections (4) and (7) by reference to the same criteria as are applied originally when setting the objective of the TSA for the trust under administration. If any commissioner does not give a statement of their agreement, then the NHS Commissioning Board has to decide whether to give a statement of its agreement to the TSA's recommendations or lay a copy of its reasons why not before Parliament. The Board will consider whether the objective of the TSA has been achieved, whether affected services at other trusts are essential and if so whether they are harmed, taking into account the views of all the local commissioners.

734. *Subsections (8), (9)* and *(11)* add to a TSA's obligations to consult (including by holding meetings) by requiring a TSA to consult: (i) other NHS trusts and NHS foundation trusts affected by wider recommendations, their staff and their commissioners; (ii) any local authority in whose area the trust in administration and other affected trusts provide goods and services; and (iii) any Local Healthwatch organisation in the area of any such local authority. "Affected trust" is defined, and what is meant by the reference to a local authority is described, in *subsection (12)*. *Subsections (10)* and *(13)* make consequential and technical amendments.

735. *Subsection (14)* requires the Secretary of State to include in the statutory guidance for a TSA appointed to an NHS trust, guidance on seeking commissioner support and involving the NHS Commissioning Board in relation to finalising the draft and final report.

736. *Subsections (15), (16) and (17)* clarify that specific statutory consultation requirements on commissioners, NHS Commissioning Board and NHS trusts and foundation trusts that apply elsewhere in the NHS Act 2006 where those bodies plan and make service change, do not apply in respect of the special administration procedure and requirements arising from it. In the context of a trust special administration, section 65H of the 2006 Act requires the TSA to consult the public and certain other specified parties before finalising the draft report setting out his or her recommendations. These amendments avoid the need for duplicatory parallel consultation by these bodies.

737. *Subsection (18)* makes consequential amendments to Schedule 14 to the Health and Social Care Act 2012 in relation to these six changes.