

CARE ACT 2014

EXPLANATORY NOTES

COMMENTARY ON SECTIONS

Part 3 - Health

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.