

HEALTH AND SOCIAL CARE ACT 2008

EXPLANATORY NOTES

TERRITORIAL EXTENT

Functions of Health Protection Agency in relation to biological substances

Section 159: Functions of Health Protection Agency in relation to biological substances

531. **Section 159** abolishes the NBSB and gives functions to the Health Protection Agency corresponding to the NBSB's functions. It also enables the Health Protection Agency to be given any other functions that could have been given to the NBSB.
532. **Subsection (1)** abolishes the NBSB and repeals the Biological Standards Act 1975. **Subsections (2) to (6)** amend the Health Protection Agency Act 2004, under which the Health Protection Agency was established and given its functions, to expand the Health Protection Agency's functions (and possible functions) to include functions in relation to biological substances.
533. **Subsection (3)** inserts a new section 2A into the Health Protection Agency Act 2004, giving the 'relevant authority' (the Secretary of State and DHSSPSNI, acting jointly) power to direct the Health Protection Agency to carry out functions in relation to biological substances. The new section 2A(3) of the Health Protection Agency Act 2004 deems the relevant authority to have directed that initially the Health Protection Agency is to acquire functions that are the same as the NBSB's: those functions are specified in the National Biological Standards Board (Functions) Order 1976. **Subsection (5)** amends section 8 (power to make transfer schemes) of the Health Protection Agency Act 2004, to enable the relevant authority to make a scheme for the transfer of the property, rights and liabilities of the NBSB to the Health Protection Agency.

Part 6 – General

Section 161: Orders, regulations and directions: general provisions

534. **Section 161** makes provision in relation to powers to make orders and regulations and to give directions under the provisions of the Act. It provides that orders and regulations made by the Secretary of State, the Treasury, the Privy Council or the Welsh Ministers are to be made by statutory instrument and that regulations made by DHSSPSNI are to be made by statutory rule. It also makes provision as to how the powers in question may be exercised.

Section 162: Orders and regulations: Parliamentary control

535. **Section 162** provides that all regulation and order making powers of the Secretary of State and the powers of the Privy Council to make an order approving rules made by the OHPA (section 109) and to make regulations about the membership of the OHPA (Schedule 6), will be subject to the negative resolution procedure, other than in the following cases:

*These notes refer to the Health and Social Care Act 2008
(c.14) which received Royal Assent on 21 July 2008*

- where subsection (3) or (4) applies, in which case the instrument must be approved by resolution of each House of Parliament; or
 - where the order is a commencement order under section 170, in which case there is no Parliamentary procedure.
536. *Subsection (3)* lists those orders and regulations of the Secretary of State which will be subject to affirmative resolution procedure. They are as follows:
- regulations defining “regulated activity” (section 8(1)) for the purposes of registration in respect of the provision of health or social care;
 - regulations under section 20 which provide for the establishment of a criminal offence carrying a maximum fine in excess of level 4 on the standard scale (currently £2,500);
 - regulations under section 43 modifying Chapter 2 of Part 1 (registration in respect of the provision of health or social care) of the Act in relation to newly regulated activities;
 - regulations made under section 87(1)(b) which provide for a penalty in excess of level 4 on the standard scale (currently £2,500);
 - the first regulations made under section 120 (additional responsibilities of responsible officers);
 - regulations making provision modifying the regulation of social care workers (section 124) or making provision modifying the functions of the GSSC in relation to the education and training of AMHPs (section 126); and
 - orders containing transitional or consequential provision (section 167) which amend or repeal any provision of an Act of Parliament.
537. *Subsection (4)* provides that the Privy Council may not, under section 109, make a statutory instrument approving rules of the OHPA that contain (either alone or with other provision) provision for the piloting of legally qualified chairs, made by virtue of section 100(4), unless a draft has been approved by a resolution of each House of Parliament.

Section 163: Orders and regulations: control by National Assembly for Wales

538. **Section 163** provides that all regulation-making powers of the Welsh Ministers, other than regulations to which subsection (3) applies, are subject to the negative resolution procedure in the National Assembly for Wales. The negative resolution procedure also applies to orders made by the Welsh Ministers under section 167(2) containing transitional or transitory provisions or savings.
539. *Subsection (3)* provides that the first regulations made under section 120 (responsible officers) and regulations making provision modifying the regulation of social care workers (section 124), or making provision modifying the functions of the CCW in relation to the education and training of AMHPs (section 126), must be approved by a resolution of the National Assembly for Wales.

Section 164: Regulations: control by Northern Ireland Assembly

540. **Section 164** provides that the first regulations made under section 120 (responsible officers) by DHSSPSNI are subject to the affirmative resolution procedure in the Northern Ireland Assembly. Subsequent regulations made under section 120 are subject to the negative resolution procedure.

Section 165: Directions

541. **Section 165** provides that any directions given by the Secretary of State or the Privy Council must be in writing and that any directions given may be varied or revoked by subsequent directions.

Section 166: Repeals

542. **Section 166** makes provision in respect of repeals. It gives effect to the repeals specified in Schedule 15.

Section 167: Power to make transitional and consequential provision etc.

543. **Section 167** confers power to make transitional or transitory provisions and savings and supplementary, incidental or consequential provision. *Subsection (1)* confers on the Secretary of State power to make by order transitional or transitory provisions and savings in connection with the commencement of any provision of the Act in relation to which the Secretary of State is the appropriate Minister for the purposes of section 170(3) (commencement). It also confers on the Secretary of State the power to make by order such supplementary, incidental or consequential provision as considered appropriate.
544. *Subsection (2)* confers on the Welsh Ministers power to make by order transitional or transitory provisions and savings in connection with the commencement of any provision of the Act in relation to which the Welsh Ministers are the appropriate Minister for the purposes of section 170(3) (commencement).
545. *Subsection (3)* provides that an order under this section may amend, repeal, revoke or otherwise modify any enactment. *Subsection (7)* defines “enactment” as an enactment contained in, or in any instrument made under, an Act of Parliament, an Act of the Scottish Parliament, a Measure or Act of the National Assembly for Wales or Northern Ireland legislation. *Subsection (5)* provides that before making an order under this section containing provision which would fall within the legislative competence of the Scottish Parliament, the Secretary of State must consult the Scottish Ministers.
546. Powers of this kind are often included in Acts which make extensive changes to existing statutory regimes. This section will ensure that necessary or expedient transitional arrangements can be made as the Act is commenced without creating any difficulty or unfairness and that there can be a smooth transition from the old law and procedures to the new.
547. A number of transitional provisions will be needed in relation to the establishment of the Commission and the assumption by it of the functions of CHAI, CSCI and MHAC. The Commission will assume the different functions of the three existing regulators over a period of time and will take on some earlier than others. Transitional provision will, for example, be needed in relation to the transition from the registration provisions of Part 2 of the Care Standards Act 2000 to the new regime under Chapter 2 of Part 1 of this Act.
548. Transitional provision will also need to be made in relation to some of the provisions in Part 2 (regulation of health professions and health and social care workforce) of the Act. This will be the case in relation to the transition from adjudication of fitness to practise cases by committees of the GMC and the GOC to their adjudication by the OHPA. Transitional provision will also have to be made in connection with: (a) preserving existing regulations, or parts of them, under the Public Health Act 1984 (Part 3 of this Act); and, (b) the abolition of the NBSB and the assumption of identical functions by the Health Protection Agency (section 159).
549. The power to make consequential amendments will enable changes made to the law by the Act to be reflected in other legislation which refers to or is dependent on provisions repealed or amended by the Act.

Section 168: Financial provisions

550. Section 168 makes provision for expenditure which will be incurred under or be attributable to the provisions of the Act to be paid out of money provided by Parliament.

Section 169: Extent

551. Section 169 makes provision as to the extent of the provisions of the Act.

Section 170: Commencement

552. Section 170 makes provision for the coming into force of the provisions of the Act. This section provides that the Act, with certain exceptions, will come into force on a day appointed by order of the appropriate authority. The exceptions to this provision are Part 6 (general) of the Act (except section 166 and Schedule 15 (repeals)), and any other provision of the Act (except section 111 or Schedule 8) so far as it confers power to make orders and regulations or defines any expression relevant to the exercise of any such power. In these cases the provisions came into force on the day on which the Act received Royal Assent.

Section 171: The appropriate authority by whom commencement order is made

553. Section 171 determines who the appropriate authority is for the purposes of making commencement orders under section 170. Except as provided by subsections (3) to (5), the appropriate authority is the Secretary of State.
554. In relation to sections 119, 120 and 122 (responsible officers), so far as they relate to Northern Ireland, the appropriate authority is DHSSPSNI.
555. In relation to the following provisions, the appropriate authority is the Welsh Ministers:
- Part 3 (public health protection), including Schedule 11, and Part 3 of Schedule 15 so far as they relate to Wales (and section 166 (repeals) so far as it relates to that Part of Schedule 15 in its application to Wales),
 - section 140 (pharmaceutical services), so far as relating to Part 2 of Schedule 12, together with that Part of that Schedule,
 - section 141(2) (remuneration for persons providing pharmaceutical services: appointment of determining authorities in relation to Wales),
 - section 144 (weighing and measuring of children: Wales),
 - subsections (1) to (7) of section 146 (direct payments in lieu of provision of care services), so far as they relate to Wales, and subsection (8) of that section,
 - section 147 (abolition of maintenance liability of relatives), Schedule 13 and Part 5 of Schedule 15, so far as they relate to local authorities in Wales (and section 166 so far as relating to Part 5 of Schedule 15 in its application to local authorities in Wales),
 - section 148 (ordinary residence for certain purposes of National Assistance Act 1948 etc.), so far as relating to Wales, and
 - the repeals in the NHS (Wales) Act 2006 in Part 4 of Schedule 15 (and section 166 so far as relating to those repeals).
556. In relation to Part 4 (health in pregnancy grant), the appropriate authority is the Treasury.

Section 172: Consultation in relation to commencement

557. **Section 172** makes provision requiring the appropriate authority for the purposes of making commencement orders under section 170 to consult others before making orders commencing certain provisions of the Act.
558. The Secretary of State must consult the Scottish Ministers before making a commencement order relating to:
- section 111 and Schedule 8 (extension of powers under section 60 of the Health Act 1999) so far as relating to-
 - subsection (2A) of section 60 of the Health Act 1999,
 - the repeal of paragraph 7(3) of Schedule 3 to that Act,
 - the amendments of paragraphs 8 and 9 of Schedule 3 to that Act, so far as relating to a profession that is not a reserved profession for Scotland,
 - the meaning of “enactment” for the purposes of Schedule 3 to that Act;
 - section 112 (standard of proof in fitness to practise proceedings) in relation to a profession that is not a reserved profession for Scotland; or
 - section 116 (powers of Secretary of State and devolved administrations), so far as relating to the functions of the Scottish Ministers.
559. Before making a commencement order relating to section 148 (ordinary residence for the purposes of the National Assistance Act 1948 etc.) in relation to England, the Secretary of State must consult the Welsh Ministers; and before making a commencement order relating to that section in relation to Wales, the Welsh Ministers must consult the Secretary of State. The Secretary of State must also consult the Welsh Ministers before making a commencement order in relation to the amendments to the powers of the Welsh Ministers under the Care Standards Act 2000 (see notes on section 95 and Schedule 5 above).
560. Before making a commencement order relating to section 159 (functions of Health Protection Agency in relation to biological substances), or Part 7 (abolition of NBSB) of Schedule 15 (or section 166 so far as relating to that Part of that Schedule), the Secretary of State must consult DHSSPSNI.