

## Health Act 2006

## **2006 CHAPTER 28**

#### PART 4

THE NATIONAL HEALTH SERVICE

## CHAPTER 1

PHARMACEUTICAL SERVICES

## 34 Power to charge

(1) After section 42 of the 1977 Act insert—

## "42A Power to charge: England

- (1) The Secretary of State may give directions to a Primary Care Trust requiring it to charge a fee in cases or descriptions of case specified in the directions to persons who make an application referred to in section 42(2)(c)(i) or (ii) to the Primary Care Trust.
- (2) The Secretary of State may in the directions—
  - (a) specify the fee himself, or
  - (b) require the Primary Care Trust to determine the amount of the fee in accordance with any requirements set out in the directions.
- (3) Before determining the amount of the fee–
  - (a) in a subsection (2)(a) case, the Secretary of State must consult such organisations as he thinks fit that appear to him to represent persons providing pharmaceutical services and such organisations as he thinks fit that appear to him to represent Primary Care Trusts,
  - (b) in a subsection (2)(b) case, the Primary Care Trust must undertake any consultation required by the directions.

- (4) The Secretary of State must publish in such manner as he thinks fit any directions he gives under this section.
- (5) In a subsection (2)(b) case, the Primary Care Trust must publish in such manner as it thinks fit the fee which it determines.

## 42B Power to charge: Wales

- (1) The National Assembly for Wales may charge a fee to persons who make an application referred to in section 42(2)(c)(i) or (ii) to the Assembly.
- (2) The Assembly may determine the amount of the fee as it thinks fit, and may in particular charge a flat fee or charge different fees in different cases or descriptions of case.
- (3) Subsections (4) and (5) apply if the Assembly directs a Local Health Board under section 16BB to exercise its functions of receiving and determining applications referred to in section 42(2)(c)(i) or (ii).
- (4) The Assembly may give directions to the Local Health Board requiring it to charge a fee in cases or descriptions of case specified in the directions to persons who make an application referred to in section 42(2)(c)(i) or (ii) to the Local Health Board.
- (5) The Assembly may in the directions—
  - (a) specify the fee itself, or
  - (b) require the Local Health Board to determine the amount of the fee in accordance with any requirements set out in the directions.
- (6) Before determining the amount of the fee—
  - (a) in a subsection (1) case, the Assembly must consult such organisations as it thinks fit that appear to it to represent persons providing pharmaceutical services,
  - (b) in a subsection (5)(a) case, the Assembly must consult such organisations as it thinks fit that appear to it to represent persons providing pharmaceutical services and such organisations as it thinks fit that appear to it to represent Local Health Boards,
  - (c) in a subsection (5)(b) case, the Local Health Board must undertake any consultation required by the directions.
- (7) The Assembly must publish in such manner as it thinks fit any fee it determines and any directions it gives under this section.
- (8) In a subsection (5)(b) case, the Local Health Board must publish in such manner as it thinks fit the fee which it determines."
- (2) In section 126 of that Act (orders and regulations, and directions), in subsection (4), before "to give directions" insert "or by section 42A or 42B above,".

## 35 Applications for provision of pharmaceutical services

In section 42 of the 1977 Act (regulations as to pharmaceutical services), after subsection (2A) insert—

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- "(2B) The regulations may include the provision mentioned in subsection (2C) for the case where—
  - (a) two or more applications referred to in subsection (2)(c)(i) or (ii) relate to the same neighbourhood,
  - (b) they are considered together by the Primary Care Trust or the National Assembly for Wales, and
  - (c) the Primary Care Trust or the Assembly would be satisfied as mentioned in subsection (2)(c) in relation to each application taken on its own, but are not so satisfied in relation to all of them taken together.
- (2C) The provision mentioned in subsection (2B) is provision for the Primary Care Trust or the Assembly, in determining which application (or applications) to grant, to take into account any proposals specified in the applications in relation to the sale or supply at the premises in question, otherwise than by way of pharmaceutical services or in accordance with a private prescription, of—
  - (a) drugs and medicines, and
  - (b) other products for, or advice in relation to, the prevention, diagnosis, monitoring or treatment of illness or handicap, or the promotion or protection of health."

## **36** Arrangements for dispensing of medicines

- (1) In section 43 of the 1977 Act (persons authorised to provide pharmaceutical services), for subsection (2) substitute—
  - "(2) Except as may be provided for by or under regulations, no arrangements for the dispensing of medicines shall be made under this Part of this Act with persons other than persons who—
    - (a) are registered pharmacists or persons lawfully conducting a retail pharmacy business in accordance with section 69 of the Medicines Act 1968; and
    - (b) undertake that all medicines supplied by them under the arrangements will be dispensed either by or under the supervision of a registered pharmacist."
- (2) In section 17S of the National Health Service (Scotland) Act 1978 (c. 29) (eligibility to be contractor under pharmaceutical care services contract), after subsection (1) insert—
  - "(1A) In such circumstances, and subject to such conditions, as may be prescribed, subsection (1) has effect with the omission of the words from "who undertakes" to the end."

#### **CHAPTER 2**

## OPHTHALMIC SERVICES

## **Provision of primary ophthalmic services**

After section 16CC of the 1977 Act insert—

### "16CD Primary ophthalmic services

- (1) Each Primary Care Trust must exercise its powers so as to provide or secure the provision, within its area, of the following primary ophthalmic services—
  - (a) the sight-testing service mentioned in subsection (2);
  - (b) such other primary ophthalmic services as may be prescribed; and
  - (c) to the extent that it considers necessary to meet all reasonable requirements, any further primary ophthalmic services.
- (2) The sight-testing service mentioned in subsection (1)(a) is a service for testing the sight of all of the following persons (except any such testing which takes place in prescribed circumstances)—
  - (a) those aged under 16;
  - (b) those aged 16, 17 or 18 who are receiving qualifying full-time education;
  - (c) those whose resources are to be treated in accordance with regulations as being less than or equal to their requirements;
  - (d) those aged 60 or over;
  - (e) those of such other description as may be prescribed.
- (3) Regulations may—
  - (a) prescribe what "qualifying full-time education" is for the purposes of subsection (2)(b);
  - (b) make provision for the purposes of subsection (2)(c) about how a person's resources and requirements are to be calculated.
- (4) A Primary Care Trust may (in addition to any other power conferred on it)—
  - (a) provide primary ophthalmic services itself (whether within or outside its area);
  - (b) make such arrangements for their provision (whether within or outside its area) as it thinks fit, and may in particular make contractual arrangements with any person.
- (5) Each Primary Care Trust must publish information about such matters as may be prescribed in relation to the primary ophthalmic services provided under this Part.
- (6) A body on which functions are conferred under this section must co-operate with any other such body in the discharge of their respective functions relating to the provision of primary ophthalmic services under this Part.
- (7) Regulations may provide that services of a prescribed description are, or are not, to be regarded as primary ophthalmic services for the purposes of this Part (but these regulations may not affect the duty in subsection (1)(a)).
- (8) Regulations under subsection (7) may in particular describe services by reference to the manner or circumstances in which they are provided.
- (9) Regulations may provide that a person—
  - (a) whose sight is tested by a person who is a party to a general ophthalmic services contract; and

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(b) who is shown during the testing or within a prescribed time after it to fall within any of paragraphs (a) to (d) of subsection (2),

is to be taken for the purposes of the testing to have so fallen immediately before his sight was tested.

- (10) In the case mentioned in subsection (9), the testing of his sight is (unless it took place in circumstances prescribed under subsection (2)) to be treated as a testing under the sight-testing service mentioned in subsection (1)(a)—
  - (a) for the purposes of remuneration in respect of the testing; and
  - (b) for any such other purpose as may be prescribed.

## 16CE Regulations under section 16CD: supplementary

- (1) Regulations under section 16CD which refer to an Act of Parliament or an instrument made under an Act of Parliament may direct that the reference is to be construed as a reference to that Act or instrument—
  - (a) as it has effect at the time when the regulations are made; or
  - (b) both as it has effect at that time and as amended subsequently.
- (2) Descriptions of persons may be prescribed under section 16CD(2)(e) by reference to any criterion, including the following—
  - (a) their age;
  - (b) the fact that a prescribed person or a prescribed body accepts them as suffering from a prescribed medical condition;
  - (c) the fact that a prescribed person or a prescribed body accepts that a prescribed medical condition from which they suffer arose in prescribed circumstances;
  - (d) their receipt of benefit in money or kind under any enactment or their entitlement to receive any such benefit;
  - (e) the receipt of any such benefit by other persons satisfying prescribed conditions or the entitlement of other persons satisfying prescribed conditions to receive such benefits.
- (3) Regulations under section 16CD(3)(b) may direct that a person's resources and requirements be calculated—
  - (a) by a method set out in the regulations;
  - (b) by a method described by reference to a method of calculating or estimating income or capital specified in an enactment other than this section or in an instrument made under an Act of Parliament or by reference to such a method but subject to prescribed modifications;
  - (c) by reference to an amount applicable for the purposes of a payment under an Act of Parliament or an instrument made under an Act of Parliament; or
  - (d) by reference to the person's being or having been entitled to payment under an Act of Parliament or an instrument made under an Act of Parliament."

#### 38 General ophthalmic services contracts

## "General ophthalmic services contracts

## 28WA General ophthalmic services contracts: introductory

- (1) A Primary Care Trust may enter into a contract under which primary ophthalmic services are provided in accordance with the following provisions of this Part.
- (2) A contract under this section is called in this Act a "general ophthalmic services contract".
- (3) Subject to any provision made by or under this Part, a general ophthalmic services contract may make such provision as may be agreed between the Primary Care Trust and the contractor or contractors in relation to—
  - (a) the services to be provided under the contract;
  - (b) remuneration under the contract; and
  - (c) any other matters.
- (4) The services to be provided under a general ophthalmic services contract may include—
  - (a) services which are not primary ophthalmic services;
  - (b) services to be provided outside the area of the Primary Care Trust.
- (5) In this Part, "contractor", in relation to a general ophthalmic services contract, means any person entering into the contract with the Primary Care Trust.

#### 28WB Persons eligible to enter into GOS contracts

- (1) A Primary Care Trust may, subject to such conditions and exceptions as may be prescribed, enter into a general ophthalmic services contract with any person.
- (2) But it may not enter into such a contract with a person who has been disqualified from doing so by an order of disqualification made by virtue of regulations under section 28WC.

#### 28WC Exclusion of contractors

- (1) The Secretary of State may make regulations conferring on a Primary Care Trust, or another prescribed person, a right to apply to the FHSAA in prescribed circumstances for an order that a person ("P") be disqualified from entering into a general ophthalmic services contract.
- (2) The regulations may in particular provide for—
  - (a) the review by the FHSAA of an order of disqualification made by virtue of regulations under this section;
  - (b) what is to happen in relation to general ophthalmic services contracts to which P is a party when the order is made.

#### 28WD GOS contracts: payments

(1) The Secretary of State may give directions as to payments to be made under general ophthalmic services contracts.

- (2) A general ophthalmic services contract must require payments to be made under the contract in accordance with directions for the time being in force under this section.
- (3) Without prejudice to the generality of the power under subsection (1), a direction under that subsection may—
  - (a) provide for payments to be made by reference to compliance with standards or the achievement of levels of performance;
  - (b) provide for payments to be made by reference to—
    - (i) any scheme or scale specified in the direction; or
    - (ii) a determination made by any person in accordance with factors specified in the direction;
  - (c) provide for the making of payments in respect of individual practitioners;
  - (d) provide that the whole or any part of a payment is subject to conditions (and may provide that payments are payable by a Primary Care Trust only if it is satisfied as to certain conditions);
  - (e) make provision having effect from a date before the date of the direction, provided that, having regard to the direction as a whole, the provision is not detrimental to the persons to whose remuneration it relates.
- (4) Before giving a direction under subsection (1), the Secretary of State—
  - (a) must consult any body appearing to him to be representative of persons to whose remuneration the direction would relate; and
  - (b) may consult such other persons as he thinks appropriate.
- (5) Section 18(1) and (3)(b) apply in relation to directions under this section.
- (6) References in this section to payments include fees, allowances, reimbursements, loans and repayments.

#### 28WE GOS contracts: other required terms

- (1) A general ophthalmic services contract must contain such provision as may be prescribed (in addition to the provision required by the preceding provisions of this Part).
- (2) Regulations under subsection (1) may in particular make provision as to—
  - (a) the manner in which, and standards to which, services are to be provided;
  - (b) the persons who perform services;
  - (c) the persons to whom services are to be provided;
  - (d) the variation of contract terms (other than terms required by or under this Part);
  - (e) rights of entry and inspection (including inspection of clinical records and other documents);
  - (f) the circumstances in which, and the manner in which, the contract may be terminated;
  - (g) enforcement;
  - (h) the adjudication of disputes.

- (3) Regulations under subsection (2)(d) may—
  - (a) make provision as to the circumstances in which a Primary Care Trust may impose a variation of contract terms;
  - (b) make provision as to the suspension or termination of any duty under the contract to provide services of a prescribed description.
- (4) Regulations making provision of the kind described in subsection (3)(b) may prescribe services by reference to the manner or circumstances in which they are provided.
- (5) Regulations under subsection (1) must make provision as to the right of persons to whom services are to be provided to choose the persons from whom they are to receive them.

## 28WF GOS contracts: disputes and enforcement

- (1) Regulations may make provision for the resolution of disputes as to the terms of a proposed general ophthalmic services contract.
- (2) Regulations under subsection (1) may make provision—
  - (a) for the referral of the terms of the proposed contract to the Secretary of State; and
  - (b) for the Secretary of State, or a person appointed by him, to determine the terms on which the contract may be entered into.
- (3) Regulations may make provision for a person or persons entering into a general ophthalmic services contract to be regarded, in circumstances where he or they so elect, as a health service body for the purposes of section 4 of the National Health Service and Community Care Act 1990, but only so far as concerns the general ophthalmic services contract (and not for any other purpose).
- (4) Regulations under subsection (3) may include provision as to the application of section 4 of that Act in cases where—
  - (a) persons practising in partnership elect to become a health service body; and
  - (b) there is a change in the membership of the partnership.
- (5) Where—
  - (a) by virtue of regulations under subsection (3), subsection (7) of section 4 of that Act applies in relation to a general ophthalmic services contract; and
  - (b) a direction as to payments is made under that provision in relation to the contract,

the direction is to be enforceable in a county court (if the court so orders) as if it were a judgment or order of that court."

## 39 Persons performing primary ophthalmic services

- (1) Section 28X of the 1977 Act (persons performing primary medical and dental services) is amended as follows.
- (2) After subsection (2) insert—

- "(2A) Regulations may provide that a health care professional of a prescribed description may not perform any primary ophthalmic service for which a Primary Care Trust is responsible unless he is included in a list maintained under the regulations by a Primary Care Trust."
- (3) In subsection (3)(b), for "medical or dental" substitute "medical, dental or ophthalmic".
- (4) After subsection (6) insert—
  - "(6A) Regulations under this section may, in particular, also prescribe the qualifications and experience which a medical practitioner who applies for inclusion in a list mentioned in subsection (2A) must have, and may—
    - (a) provide for the practitioner to show to the satisfaction of a committee recognised by the Secretary of State for the purpose that he possesses such qualifications and experience;
    - (b) confer on a person who is dissatisfied with the determination of such a committee a right of appeal to a committee appointed by the Secretary of State; and
    - (c) provide for anything which appears to the Secretary of State to be appropriate in connection with that right of appeal."
- (5) In the heading, for "medical and dental" substitute "medical, dental and ophthalmic".

## 40 Assistance and support

- (1) Section 28Y of the 1977 Act (assistance and support for providers of primary medical and dental services) is amended as follows.
- (2) For paragraph (a) of subsection (1) substitute—
  - "(a) any person providing, or proposing to provide, primary medical services under a general medical services contract, primary dental services under a general dental services contract, or primary ophthalmic services under a general ophthalmic services contract;".
- (3) In paragraph (b) of subsection (1), for "such services" substitute "primary medical or dental services".

## 41 Local Optical Committees

After section 45B of the 1977 Act insert—

## "45C Local Optical Committees: England

- (1) A Primary Care Trust may recognise a committee formed for its area, or for its area and that of one or more other Primary Care Trusts, which it is satisfied is representative of—
  - (a) the persons to whom subsection (2) applies; and
  - (b) the persons to whom subsection (3) applies.
- (2) This subsection applies to every person who, under a general ophthalmic services contract entered into by him, is providing primary ophthalmic services in the area for which the committee is formed.

- (3) This subsection applies to every optometrist not falling within subsection (2)—
  - (a) who is performing primary ophthalmic services in the area for which the committee is formed, whether under section 16CD(4)(a) above, or under a general ophthalmic services contract; and
  - (b) who has notified the Primary Care Trust that he wishes to be represented by the committee (and has not notified it that he wishes to cease to be so represented).
- (4) A committee recognised under this section shall be called the Local Optical Committee for the area for which it is formed.
- (5) Any such committee may delegate any of its functions, with or without restrictions or conditions, to sub-committees composed of members of that committee.
- (6) Any such committee may co-opt persons not falling within subsection (2) or (3) on such terms as it thinks fit.
- (7) Regulations may require a Primary Care Trust, in the exercise of its functions relating to primary ophthalmic services, to consult any committee recognised by it under this section on such occasions and to such extent as may be prescribed.
- (8) A committee recognised under this section shall have such other functions as may be prescribed.
- (9) A committee recognised under this section shall in respect of each year determine the amount of its administrative expenses for that year.
- (10) A Primary Care Trust may—
  - (a) on the request of a committee recognised by it, allot to that committee such sums as it may determine for defraying the committee's administrative expenses; and
  - (b) deduct the amount of such sums from the remuneration of persons of whom it is representative under subsection (1)(a) under the general ophthalmic services contracts entered into by them with the Trust.
- (11) References in this section to the administrative expenses of a committee include the travelling and subsistence allowances payable to its members."

## 42 Payments in respect of optical appliances

- (1) Schedule 12 to the 1977 Act (which makes provision about charges and payments) is amended as follows.
- (2) In paragraph 2A(1)—
  - (a) for paragraph (b) substitute—
    - "(b) for a person whose resources fall to be treated under the regulations as being less than or equal to his requirements;
    - (ba) for any person falling within section 16CD(2)(d) above; or",
  - (b) after "paragraph (a), (b)" insert ", (ba)".
- (3) After paragraph 2A insert—

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- "2B (1) Regulations under paragraph 2A above providing for payments for meeting or contributing towards the cost incurred for the supply of optical appliances or their replacement or repair may also provide as follows, but in relation to England only.
  - (2) They may make provision for such payments not to be made to any person falling within a prescribed description.
  - (3) They may make provision for the Secretary of State to give notice as mentioned in sub-paragraph (4) to a person to whom such payments have been made (whether by the Secretary of State or by an authority established under this Act).
  - (4) Such a notice is notice that no further such payments in respect of the supply, replacement or repair of optical appliances at a particular location or in a particular area, in either case specified in the notice, will be made to him after a date specified in the notice.
  - (5) If such a notice is given, no further payments as mentioned in subparagraph (4) are to be made to him after the date specified in the notice, unless the notice is cancelled by the Secretary of State.
  - (6) The regulations may make provision conferring on the Secretary of State the right, if he has given a notice by virtue of sub-paragraph (3), to apply to the FHSAA for a stop order.
  - (7) A stop order is an order that no further such payments are to be made (whether by the Secretary of State or by any authority established under this Act) to the person in question in respect of the supply, replacement or repair of optical appliances, wherever the supply, replacement or repair occurred.
  - (8) If the regulations make the provision mentioned in sub-paragraph (3), they must also make provision conferring prescribed rights of appeal to the FHSAA upon the person to whom the notice was given."

## 43 General ophthalmic services: transitional

- (1) The Secretary of State shall in regulations make transitional provision in respect of persons who, immediately before the coming into force of section 38 of this Act, are providing services in England under section 38 of the 1977 Act (general ophthalmic services).
- (2) Regulations under this section may provide that, in such circumstances as the regulations may specify, a Primary Care Trust must, if any such person so wishes, enter into a general ophthalmic services contract with him; and the regulations may make provision as to the terms of any such contract.
- (3) Regulations under this section may provide that, in such circumstances as the regulations may specify, a Primary Care Trust must, if any such person so wishes, enter into a contract with him, containing such terms as the regulations may specify, for the provision of ophthalmic services.
- (4) Regulations under this section may make provision for the resolution of disputes in relation to any contract entered into, or proposed to be entered into, under

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- subsection (2) or (3), including provision for the determination of disputes by the Secretary of State or a person appointed by him.
- (5) Regulations under this section may make provision in respect of a period beginning before the coming into force of the provision (or of section 38 of this Act), but such provision must not as a whole be detrimental to the remuneration of the persons to whom it relates.
- (6) In this section, "general ophthalmic services contract" means a contract under section 28WA of the 1977 Act (as inserted by section 38(1)).

#### **CHAPTER 3**

PROTECTION OF NHS FROM FRAUD AND OTHER UNLAWFUL ACTIVITIES

#### **Preliminary**

# 44 Compulsory disclosure of documents for purposes of counter fraud or security management functions

- (1) This Chapter confers power to require the production of documents in connection with the exercise of—
  - (a) the appropriate national authority's counter fraud functions in relation to the health service in England or (as the case may be) Wales, or
  - (b) the Secretary of State's security management functions in relation to the health service in England.
- (2) The appropriate national authority's "counter fraud functions" in relation to the health service in England or Wales means that authority's power (by virtue of section 2(b) of the 1977 Act) to take action for the purpose of preventing, detecting or investigating fraud, corruption or other unlawful activities carried out against or otherwise affecting—
  - (a) the health service in England or (as the case may be) Wales, or
  - (b) that authority in relation to the authority's responsibilities for the health service in England or (as the case may be) Wales.
- (3) The Secretary of State's "security management functions" in relation to the health service in England means the Secretary of State's power (by virtue of section 2(b) of the 1977 Act) to take action for the purpose of protecting and improving the security of—
  - (a) persons employed by the Secretary of State or an NHS body in the provision of services for the purposes of the health service in England ("English NHS services");
  - (b) health service providers and persons employed by them so far as they or (as the case may be) persons so employed are engaged in any activity directly related to the provision of English NHS services;
  - (c) NHS contractors and persons employed by them so far as they or (as the case may be) persons so employed are engaged in any activity directly related to the provision of English NHS services;

- (d) persons not within paragraphs (a) to (c) who work in any capacity on premises used by the Secretary of State, an NHS body, a health service provider, or an NHS contractor, in connection with the provision of English NHS services;
- (e) persons on such premises—
  - (i) who are there for the purpose of receiving, or are receiving or have received, treatment or other services as patients, or
  - (ii) who are accompanying persons within sub-paragraph (i);
- (f) property and information used or held by the Secretary of State, an NHS body, a health service provider, or an NHS contractor, in connection with the provision of English NHS services.
- (4) In this Chapter—
  - (a) the appropriate national authority's counter fraud functions in relation to the health service in England or (as the case may be) Wales, and
  - (b) the Secretary of State's security management functions in relation to the health service in England,

are collectively referred to as functions to which this Chapter applies.

(5) In this section "investigating" means investigating in relation to civil or criminal proceedings.

## 45 Meaning of "NHS body" etc.

- (1) This section applies for the purposes of this Chapter.
- (2) Subject to subsection (3), an "NHS body" means—
  - (a) a Strategic Health Authority,
  - (b) a Local Health Board,
  - (c) a Special Health Authority,
  - (d) a Primary Care Trust,
  - (e) an NHS trust, or
  - (f) an NHS foundation trust.
- (3) In section 44(3), and in section 46(1) so far as having effect in relation to the Secretary of State's security management functions referred to in section 44(3), an "NHS body" means—
  - (a) a Strategic Health Authority,
  - (b) a Special Health Authority so far as performing functions in respect of England,
  - (c) a Primary Care Trust,
  - (d) an NHS trust all or most of whose hospitals, establishments and facilities are situated in England, or
  - (e) an NHS foundation trust.
- (4) A "health service provider" means any person (other than a body within subsection (2)) providing primary medical services, primary dental services, primary or general ophthalmic services, or pharmaceutical services.
- (5) An "NHS contractor" means any person (other than a body or person within subsection (2) or (4)) providing services of any description under arrangements made with an NHS body.

- (6) A "statutory health body" means any body (other than a body within subsection (2), (4) or (5)) established by or under an enactment and—
  - (a) providing services in connection with the provision of, or
  - (b) exercising functions in relation to,

the health service in either England or Wales or both.

- (7) The appropriate national authority may by order—
  - (a) make such amendments of any of subsections (2) to (6) as the authority considers appropriate;
  - (b) make such consequential amendments of this Chapter as the authority considers appropriate.

#### Disclosure notices

## 46 Notice requiring production of documents

- (1) This section applies if it appears to the appropriate national authority that there are reasonable grounds for suspecting—
  - (a) that any documents containing information relevant to the exercise of any of the authority's functions to which this Chapter applies are in the possession or under the control of any NHS body, statutory health body, health service provider or NHS contractor ("the relevant organisation"), and
  - (b) that a person within subsection (3) is accountable for the documents.
- (2) The appropriate national authority may serve on that person a notice requiring him to produce the documents to an authorised officer.
- (3) The persons within this subsection are—
  - (a) any member, officer or director of the relevant organisation;
  - (b) any other person who takes part in the management of the affairs of that organisation;
  - (c) any person employed by that organisation; and
  - (d) (in the case of a health service provider or NHS contractor who is an individual) that individual.
- (4) A notice under this section must specify or describe the documents to which it relates.
- (5) Subject to subsections (6) and (7), the notice may require those documents to be produced—
  - (a) at or by such time as is specified in the notice, or at once, and
  - (b) at such place, and in such manner, as is so specified.
- (6) When specifying a time at or by which the documents are to be produced, the notice must not require them to be produced otherwise than at a reasonable hour.
- (7) If the notice requires documents to be produced at once, it may only be served at a reasonable hour.
- (8) An authorised officer may, by agreement with the person served with a notice within subsection (6) or (7), vary the notice so as to extend the time for compliance with it.

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- (9) Any notice under this section, and any variation of such a notice under subsection (8), must be in writing.
- (10) For the purposes of this section an individual is "accountable" for any documents if he has either day-to-day, or an overall, responsibility for the custody or control of the documents

#### 47 Production of documents

- (1) This section applies where a notice has been served under section 46.
- (2) An authorised officer may—
  - (a) take away any documents produced in compliance with the notice;
  - (b) take copies of or extracts from any documents so produced;
  - (c) require the person producing any such documents to provide an explanation of any of them.

## (3) If—

- (a) the officer takes away any such document, and
- (b) the person producing it requests the officer to provide him with a copy of it, and
- (c) the request appears to the officer to be reasonable in the circumstances, the officer must, as soon as is reasonably practicable, provide that person with a copy of the document (in such form as the officer considers appropriate).
- (4) Documents produced in compliance with a notice under section 46 may be retained for so long as the appropriate national authority considers that it is necessary to retain them (rather than copies of them) in connection with the exercise of any function of the authority to which this Chapter applies.
- (5) If the appropriate national authority has reasonable grounds for believing—
  - (a) that any such documents may have to be produced for the purposes of any legal proceedings, and
  - (b) that they might otherwise be unavailable for those purposes, they may be retained until the proceedings are concluded.
- (6) If a person who is required by a notice under section 46 to produce any documents does not produce the documents in compliance with the notice, an authorised officer may require that person to state, to the best of his knowledge and belief, where they are.
- (7) A person is not bound to comply with any requirement imposed by a notice under section 46 or any requirement under subsection (6) unless evidence of authority is given—
  - (a) at the time when the notice is served, or
  - (b) at the time when the requirement is imposed under subsection (6), as the case may be.
- (8) In addition, a person may not be required under section 46 or subsection (6) to produce any document or disclose any information which he would be entitled to refuse to produce or disclose in proceedings in the High Court on grounds of legal professional privilege.

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## 48 Delegation of functions

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- (1) The appropriate national authority may direct a Special Health Authority to exercise so much of the appropriate national authority's functions under sections 46 and 47 as is specified in the directions ("the delegated functions").
- (2) The appropriate national authority may give directions providing for senior officers of the Authority to exercise the delegated functions on behalf of the Authority.
  - "Senior officer" means an officer of or above a level specified in the directions.
- (3) Any directions under subsection (1) or (2) must be given in regulations made by the appropriate national authority.
- (4) The appropriate national authority may by regulations make such provision as the authority considers appropriate in connection with the exercise of the delegated functions.
- (5) The regulations may, in particular, make provision—
  - (a) specifying conditions as to training that must be satisfied in relation to officers of the Authority involved in the exercise of the delegated functions;
  - (b) for requiring officers to obtain specific authorisation before the delegated functions are exercised in relation to personal records;
  - (c) providing for the designation of officers for the purpose of giving such authorisations;
  - (d) otherwise prescribing the manner in which the delegated functions may be exercised.
- (6) If the appropriate national authority gives a direction under subsection (1), the 1977 Act has effect as if—
  - (a) the direction is a direction of the authority under section 16D of that Act; and
  - (b) the delegated functions are exercisable by the Special Health Authority under section 16D.

#### 49 Code of practice relating to delegated functions

- (1) The appropriate national authority may issue a code of practice relating to—
  - (a) the exercise of functions by or on behalf of a Special Health Authority by virtue of directions under section 48;
  - (b) procedures to be followed in relation to the disclosure (in accordance with sections 50 and 51) of information obtained by or on behalf of a Special Health Authority in the exercise of such functions.
- (2) The appropriate national authority must keep the code under review and may from time to time—
  - (a) revise the whole or any part of the code, and
  - (b) issue a revised code.
- (3) Where the appropriate national authority proposes to issue a code of practice under this section, the authority must—
  - (a) prepare a draft of the code, and
  - (b) consult such persons as the authority considers appropriate about the draft.

- (4) Where the appropriate national authority proposes to issue a revised code under this section which in the opinion of the authority would result in a substantial change in the code, the authority must—
  - (a) prepare a draft of the revised code, and
  - (b) consult such persons as the authority considers appropriate about the change.
- (5) Where, following consultation under subsection (3) or (4), the appropriate national authority issues the code or revised code (whether in the form of the draft or with such modifications as the authority thinks fit), it comes into force at the time when it is issued by the authority.
- (6) A failure to observe any provision of a code or revised code issued under this section does not of itself make a person liable to any criminal or civil proceedings.
- (7) A code or revised code issued under this section is admissible in evidence in any criminal or civil proceedings.
- (8) Consultation undertaken by the appropriate national authority before the commencement of this section is as effective for the purposes of this section as consultation undertaken after that time.

#### 50 Disclosure of information

- (1) This section applies to information which—
  - (a) is held by or on behalf of the appropriate national authority, and
  - (b) was obtained by virtue of section 46 or 47.
- (2) The information must not be disclosed except in accordance with subsection (3).
- (3) A disclosure is made in accordance with this subsection if it is made—
  - (a) for the purposes of the exercise of any of the appropriate national authority's functions in relation to the health service in England or (as the case may be) Wales,
  - (b) for the purposes of any civil proceedings brought in the exercise of any of those functions,
  - (c) for the purposes of any criminal investigation or proceedings,
  - (d) for the purposes of any relevant disciplinary proceedings, or
  - (e) in accordance with an enactment or order of a court or tribunal.

### (4) In subsection (3)—

- (a) paragraphs (a) and (b) apply whether or not the appropriate national authority concerned is the one mentioned in subsection (1), and
- (b) "relevant disciplinary proceedings" means disciplinary proceedings conducted in relation to an individual by—
  - (i) an NHS body, statutory health body or health service provider, or
  - (ii) any of the regulatory bodies mentioned in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002 (c. 17) (bodies within remit of Council for the Regulation of Health Care Professionals).

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- (5) Where information to which this section applies is disclosed to any person in accordance with subsection (3), the information must not be used or further disclosed except—
  - (a) for a purpose connected with the functions, investigation or proceedings for the purposes of which it was so disclosed, or
  - (b) in accordance with an enactment or order of a court or tribunal.
- (6) Information to which this section applies may be disclosed in accordance with subsection (3) despite any obligation of confidence that would otherwise prohibit or restrict the disclosure.
- (7) This section does not prohibit any disclosure or use of information relating to a particular person if it is made with the consent of that person.

## 51 Protection of personal information disclosed for purposes of proceedings

- (1) Information obtained from personal records produced in compliance with a notice under section 46 is "protected information" for the purposes of this section if—
  - (a) a person ("the discloser"), in accordance with section 50(3), discloses the information for the purposes of any proceedings, and
  - (b) either—
    - (i) the identity of the individual in question can be ascertained from the information itself, or
    - (ii) the discloser has reasonable cause to believe that it will be possible for a person who obtains the information as a direct or indirect consequence of the disclosure to ascertain the individual's identity from that information taken with other information obtained by virtue of section 46 or 47 and disclosed by or on behalf of the appropriate national authority.
- (2) The discloser must take all reasonable steps to ensure that, once disclosed by him in accordance with section 50(3), the protected information is not further disclosed to any person who is not someone to whom it is necessary to disclose the information for any purpose connected with the proceedings mentioned in subsection (1)(a).
- (3) In subsection (2) the reference to further disclosure of the information does not include any such disclosure—
  - (a) by way of evidence in any proceedings, or
  - (b) in accordance with an enactment or order of a court or tribunal.
- (4) The appropriate national authority must make provision, whether in a code of practice issued under section 49 or otherwise, for requiring any person disclosing protected information in accordance with section 50(3) to ensure, by the use of a distinguishing mark or in some other way, that the information is clearly identified as protected information for the purposes of this section.
- (5) Information that appears to be protected information must not be disclosed by way of evidence in any proceedings unless—
  - (a) the whole of the proceedings are held in private, or
  - (b) in any other case, the information is disclosed in accordance with permission given by the court or tribunal on an application under subsection (6).
- (6) If, on an application by a party to—

- (a) proceedings before a court, or
- (b) proceedings of any description before a tribunal that sits, or may sit, in public during the whole or part of proceedings of that description,

the court or tribunal is satisfied that it is in the interests of justice for any information that appears to be protected information to be disclosed by way of evidence in the proceedings, it may give permission for the information to be so disclosed, on such terms as it thinks fit.

- (7) When determining such an application, the court or tribunal must consider whether, in the interests of protecting the identity of the individual to whom the information relates, the whole or part of the proceedings should be held in private.
- (8) If the court or tribunal is satisfied that the whole or part of the proceedings should be held in private, it must give such directions, or take such other steps, as appear to it to be appropriate.
- (9) In this section "proceedings" means—
  - (a) criminal or civil proceedings, or
  - (b) relevant disciplinary proceedings (as defined by section 50(4)).

## Offences

## 52 Offences in connection with production of documents

- (1) A person commits an offence if, without reasonable excuse, he fails to comply with any requirement imposed on him under section 46 or 47.
- (2) A person guilty of an offence under subsection (1) is liable on summary conviction—
  - (a) to imprisonment for a term not exceeding 51 weeks, or
  - (b) to a fine not exceeding level 3 on the standard scale, or to both.
- (3) If a person is convicted of an offence under subsection (1) in respect of a failure to produce a document and the failure continues after the date of his conviction, the person—
  - (a) commits a further offence, and
  - (b) is liable on summary conviction to a fine not exceeding 2% of level 3 on the standard scale for each day on which the failure so continues.
- (4) A person commits an offence if, in purported compliance with any requirement imposed on him under section 47—
  - (a) he makes a statement which is false or misleading, and
  - (b) he either knows that it is false or misleading or is reckless as to whether it is false or misleading.

"False or misleading" means false or misleading in a material particular.

- (5) A person guilty of an offence under subsection (4) is liable—
  - (a) on conviction on indictment, to imprisonment for a term not exceeding two years or to a fine, or to both;
  - (b) on summary conviction, to imprisonment for a term not exceeding 12 months or to a fine not exceeding the statutory maximum, or to both.

## 53 Offences relating to disclosure or use of information

- (1) A person commits an offence if he fails to comply with section 50(2) or (5) or section 51(2).
- (2) A person guilty of an offence under subsection (1) is liable—
  - (a) on conviction on indictment, to imprisonment for a term not exceeding two years or to a fine, or to both;
  - (b) on summary conviction to imprisonment for a term not exceeding 51 weeks or to a fine not exceeding the statutory maximum, or to both.
- (3) It is a defence for a person charged with an offence under subsection (1) in respect of a disclosure of information to prove that at the time of the alleged offence—
  - (a) any of the circumstances in subsection (4) applied, or
  - (b) he reasonably believed that they applied.
- (4) The circumstances referred to in subsection (3) are—
  - (a) that the disclosure was lawful,
  - (b) that the information had already been lawfully made available to the public,
  - (c) that the disclosure was necessary or expedient for the purpose of protecting the welfare of any individual,
  - (d) that the disclosure was made in a form in which no person to whom the information relates is identified.
- (5) Subsection (4)(d) is not satisfied if the identity of any such person can be ascertained either—
  - (a) from the information itself, or
  - (b) from that information taken with other information obtained by virtue of section 46 or 47 and disclosed by or on behalf of the appropriate national authority.

#### Supplementary

### Manner in which disclosure notice may be served

- (1) This section provides for the manner in which a notice may be served under section 46.
- (2) The notice may be served on a person by—
  - (a) delivering it to him;
  - (b) leaving it at his proper address;
  - (c) sending it by post to him at that address.
- (3) For the purposes of this section and section 7 of the Interpretation Act 1978 (c. 30) (service of documents by post) in its application to this section, the proper address of a person is his usual or last-known address (whether residential or otherwise), except that—
  - (a) in the case of a notice to be served on the secretary, clerk or similar officer of a body corporate, it is the address of the registered office of that body or its principal office in the United Kingdom,
  - (b) in the case of a notice to be served on a partner or a person having the control or management of a partnership business, it is the address of the principal office of the partnership in the United Kingdom, and

(c) in the case of a notice to be served on an officer of an unincorporated association (other than a partnership), it is the address of the principal office of the association in the United Kingdom.

## 55 Interpretation

(1) In this Chapter—

"authorised officer", in relation to any function, means (subject to subsection (5)) an officer of the appropriate national authority authorised by the authority to act in exercise of the function;

"document" means anything in which information of any description is recorded;

"employed" means employed whether under a contract of service or a contract for services or otherwise, and whether for remuneration or not;

"functions to which this Chapter applies" has the meaning given by section 44(4);

"health service provider", "NHS body" and "NHS contractor" have the meanings given by section 45;

"personal records" has the meaning given by section 12 of the Police and Criminal Evidence Act 1984 (c. 60);

"statutory health body" has the meaning given by section 45.

- (2) Other expressions used in this Chapter which are also used in the 1977 Act have the same meanings as in that Act.
- (3) References in this Chapter to the provision of services—
  - (a) in relation to statutory health bodies, health service providers or NHS contractors, include references to the provision of goods or facilities, and
  - (b) include references to the provision of services (or goods or facilities) wherever that takes place.
- (4) In relation to information recorded otherwise than in legible form, any reference in this Chapter to the production of documents is a reference to the production of a copy of the information in legible form.
- (5) Where functions of the appropriate national authority are exercisable by a Special Health Authority by virtue of directions under section 48—
  - (a) references in this Chapter to authorised officers include officers of the Special Health Authority authorised by or on behalf of the Authority to act in exercise of the functions, and
  - (b) references in this Chapter to information held or disclosed by or on behalf of the appropriate national authority include information held or disclosed by or on behalf of the Special Health Authority.

## **CHAPTER 4**

#### **A**UDIT

## 56 Accounts and audit

(1) For section 98 of the 1977 Act substitute—

## "98 Accounts and audit

Schedule 12B to this Act makes provision about the accounts of certain health service bodies and the auditing of such accounts."

(2) After Schedule 12A to that Act insert, as Schedule 12B, the Schedule set out in Schedule 3 to this Act.