

NATIONAL HEALTH SERVICE, ENGLAND AND WALES

Directions and Consolidating Directions to the National Institute for Health and Clinical Excellence 2005

The Secretary of State for Health in exercise of the powers conferred by sections 16D,17 and 126(4) of the National Health Service Act 1977(a) and of all other powers enabling him in that behalf, hereby gives the following Directions:

Application, commencement and interpretation

1.—(1) These Directions are given to the National Institute for Health and Clinical Excellence(b).

(2) These Directions shall come into force on 1st April 2005.

(3) These Directions apply in relation to England.

(4) In these Directions—

“the Act” means the National Health Service Act 1977;

“interventional procedure” means a procedure which is used for treatment requiring a patient to undergo one or more of the following: an incision, a puncture, an entry into a body cavity or requiring a patient to be subjected to electromagnetic energy or acoustic energy;

“the Institute” means the National Institute for Health and Clinical Excellence;

“notified” means registered with the Institute in accordance with the Institute’s procedure for registration;

“a patient” means any person who receives treatment;

“treatment” includes prevention, examination and diagnosis.

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- (a) 1977 c.49; section 16D was substituted by section 12(1) of the 1999 Act and amended by sections 1(3) and 3(1) and (2) of, and paragraphs 1 and 6(a) of Part 1 of Schedule 1 to, the National Health Service Reform and Health Care Professions Act 2002 (c.17) (“the 2002 Act”); section 17 was substituted by section 12(1) of the 1999 Act and amended by section 1(3) of, and paragraphs 1 and 7 of Part 1 of Schedule 1 to, the 2002 Act and section 67(1) of, and paragraphs 5(1) and (3) of Part 1 of Schedule 5 to, the Health and Social Care Act 2001 (c.15) (“the 2001 Act”); section 126(4) was amended by section 65(2) of the National Health Service and Community Care Act 1990 (c.19) (“the 1990 Act”), by paragraph 37(6) of Schedule 4 to the Health Act 1999 (c.8) and by paragraph 5(13)(b) of Part 1 of Schedule 5 to the 2001 Act, sections 6(3)(c) and 37(1) of, and paragraphs 1 and 10a of Schedule 8 to, the 2002 Act and section 184 of and paragraph 38 of Schedule 11 and Part 4 of Schedule 14 to the Health and Social Care (Community Health and Standards) Act 2003 (c.43) (“the 2003 Act”). The functions of the Secretary of State under these provisions are, so far as exercisable in relation to Wales, transferred to the National Assembly for Wales by article 2(a) of the National Assembly for Wales (Transfer of Functions) Order 1999 (the Transfer Order), S.I. 1999/672; see the entry in Schedule 1 for the National Health Service Act 1977 as amended by section 66(4) and (5)(a) of the 1999 Act, section 67(1) of, and paragraph 12(1) and (3) of Schedule 5 to, the 2001 Act and section 196 of, and Part 4 of Schedule 14 to the 2003 Act. These Directions are issued by the Secretary of State in exercise of concurrent powers with the National Assembly for Wales. See Article 2(c) of the Transfer Order.
- (b) The National Institute for Health and Clinical Excellence was established by S.I. 1999/220 as amended by 1999/2219, 2002/1760 and 2005/ 497.

Functions of the Institute

2.—(1) The Secretary of State directs the Institute to exercise the following functions in connection with the promotion of clinical excellence and the effective use of available resources in the health service—

- (a) to appraise the clinical benefits and the costs of such health care interventions as may be notified by the Secretary of State and to make recommendations;
- (b) to develop guidelines providing advice on good practice in the management of such diseases and conditions as may be notified by the Secretary of State;
- (c) to provide such information and instruction on the implementation of the recommendations and guidelines referred to in sub- paragraphs (a) and (b) above to persons employed in activities connected with the health service as may be conducive to their efficiency in relation to such employment;
- (d) to include in the recommendations and guidelines referred to in sub-paragraphs (a) and (b) above guidance on clinical audit criteria;
- (e) to disseminate, as appropriate and via an appropriate range of media, such recommendations and guidelines referred to in sub-paragraphs (a) and (b) above to the health service and to the general public;
- (f) to look into and consider, for the purpose of advising the Secretary of State with regard to possible improvements in the provision of health services and in the effective use of available resources, such other matters as may be notified by the Secretary of State;
- (g) to provide information on medicines and prescribing through the National Prescribing Centre (NPC) (a);
- (h) to consider all interventional procedures notified to the Institute;
- (i) to identify any interventional procedure notified to the Institute for which an assessment by the Institute as to whether it is safe and efficacious for use in the health service is unnecessary;
- (j) to identify any interventional procedure notified to the Institute that does not fall within sub-paragraph (b) for which a comprehensive review of the evidence is required to enable the Institute to evaluate the procedure in accordance with sub-paragraph (e);
- (k) to assess the extent to which any interventional procedure notified to the Institute that does not fall within either of sub-paragraphs (h) or (i) is safe and efficacious for use in the health service and to issue guidance to the health service on the use of such a procedure;
- (l) to evaluate the safety and efficacy of any interventional procedure identified under sub-paragraph (j) for the purposes of use in the health service and to issue guidance to the health service on the use of such a procedure;
- (m) to provide administrative support to the Advisory Committee on Borderline Substances (ACBS)(b) to enable the Committee to carry out its functions

for the purpose of this direction “to evaluate” in sub-paragraph (l) shall include a comprehensive analysis of the available academic and clinical evidence and the collection and analysis of any new clinical data that may be made available by the health service.

(a) The publications MeReC Bulletin, MeReC Extra and MeReC briefing are produced by the NPC a unit of the Department of Health.

(b) The Advisory Committee on Borderline Substances is a non statutory body established to provide independent advice to the Secretary of State for Health on NHS prescribing of products which are not classified as drugs or devices.

(2) The Secretary of State directs the Institute to exercise the following functions in connection with the promotion of excellence in public health provision and promotion and the effective use of resources available in the health service and other available public funds—

- (a) to develop, maintain and disseminate an evidence-base for effective public health action on health improvement and the reduction of inequalities in health in line with the Secretary of State's priorities for health as notified from time to time;
- (b) to provide guidance on the development and setting of standards for public health and health promotion programmes and practice and support their implementation;
- (c) to provide guidance on the means for improving the capability and capacity of organisations, systems and the wider public health workforce to deliver health improvement and reduce inequalities in health;
- (d) to advise and assist in relation to such other matters as may be notified by the Secretary of State from time to time;
- (e) to disseminate, as appropriate and via an appropriate range of media, the guidance referred to in sub-paragraphs (b) and (c) above.

(3) In addition to the functions described in paragraph (1) above the Institute may, subject to the approval of the Secretary of State, consider and, as appropriate, endorse guidance prepared by other bodies concerning the clinical benefits of health care interventions and good practice in the management of diseases and other conditions affecting health.

(4) In exercising the functions described in paragraphs (1)(a) – (d) and (3) above the Institute shall have regard to the following factors-

- (a) the broad balance of clinical benefits and costs;
- (b) the degree of clinical need of patients with the condition or disease under consideration;
- (c) any guidance issued to the NHS by the Secretary of State that is specifically drawn to the attention of the Institute by the Secretary of State and any guidance issued by the Secretary of State;
- (d) the potential for long term benefits to the NHS of innovation.

(5) To develop a process to enable the Institute to ascertain and take into account the views of the general public in connection with the exercise of the functions set out in this paragraphs (1)(a) –(d) and (3).

General Functions of the Institute

3. The institute may exercise functions under —

- (a) section 23 of the 1977 Act (voluntary organisations and other bodies); and
- (b) section 2(b) of the 1977 Act (Secretary of State's general powers as to services) to do anything whatsoever which is calculated to facilitate, or is conducive or incidental to, the discharge of the Institute's functions.

Appointment of Committees

4. The Secretary of State directs the Institute to appoint in accordance with regulation 9(1) of the National Institute for Clinical Excellence Regulations 1999(a) a Committee to be known as the Partners Council.

Appeal Arrangements

5. The Secretary of State directs the Institute to make arrangements for holding appeals, on the application of persons aggrieved by recommendations made by the Institute under paragraph

(a) S.I.1999/260 as amended by S.Is 1999/2218,2002/1759,2004/596 and 2005/498.

2(1)(a), on the grounds that the Institute has failed to act fairly, has exceeded its powers or has formulated guidance which cannot reasonably be justified.

Land Transactions

6.—(1) Subject to sub-paragraphs (3) and (4) of this paragraph the Institute shall exercise the functions of the Secretary of State under section 87(1) and (2) of the Act only so far as is necessary to enable it to secure and maintain such accommodation as it requires for the proper discharge of its other functions.

(2) The functions mentioned in sub paragraph (1) of this paragraph do not include the powers of the Secretary of State to acquire land compulsorily.

(3) The Institute shall not without the prior approval of the Secretary of State exercise the functions mentioned in sub-paragraph (1) of this paragraph so as to—

- (a) acquire or dispose of any land, or any interest in land, the value of which exceeds £1million; or
- (b) acquire a leasehold interest where-
 - (i) the term of the lease is less than one year and the rent payable exceeds £1million; or
 - (ii) the term of the lease is not less than one year and the product of multiplying the number of years in the term by the amount of rent payable in the first year of the term exceeds £1million.

(4) In sub paragraph 3(a) above, “value” means the value on a disposal by sale with vacant possession on the open market.

(5) In sub-paragraph 3(b) above, “the term” in relation to a leasehold interest acquired by way of assignment means the unexpired term.

7. Any function of the Secretary of State, under section 87 of the Act shall be exercised in accordance with the procedures and instructions for the time being in force and issued by the Department of Health in the document entitled “Estatecode – essential guidance on estates and facilities management”(a), except in so far as such procedures and instructions are inconsistent with these Directions.

8. Subject to the Institute obtaining approval as and when required under paragraph 6(3), where the exercise by the Institute of any function to which these Directions apply requires—

- (a) the execution under seal of any document, the Institute shall execute such document on behalf of the Secretary of State under its own seal;
- (b) the execution of a document otherwise than under seal, the Institute shall make arrangements for an officer of the Institute who has been duly authorised for the purpose to sign the document for the Institute on behalf of the Secretary of State.

Accounts and annual reports

9.—(1) The Institute must prepare and keep annual accounts in respect of each financial year which shall give a true and fair view of the income and expenditure and cash flows of the Institute for the financial year, and the state of affairs as at the year end.

(2) The accounts shall be prepared in accordance with—

- (a) the Resource Accounting Manual(b);
- (b) the Department of Health Special Health Authority Manual for Accounts(c)

(a) Copies of this document are available from NHS Estates, 1 Trevelyan Square, Leeds LS16AE.

(b) This document is published by HM Treasury and are available on the website www.resource-accounting.gov.uk/current/frames.htm

(c) This document is available on the website www.info.doh.gov.uk/doh/finman.nsf.

(c) any other requests made by the Secretary of State,

except where agreed with the Secretary of State in which case the exception shall be disclosed in the notes to the accounts.

(3) The Agency must prepare an annual report in relation to its activities and send a copy of its report for that financial year to the Secretary of State by 30th November in the financial year following the financial year to which the report relates.

Revocation

10.The Directions to the Institute dated 6th August 1999, 9th December 1999, 9 March 2000, 27th March 2002 and 17 February 2003 are hereby revoked.

Signed by authority of the Secretary of State

31 March 2005

A handwritten signature in black ink, appearing to be 'Shu' or similar, written in a cursive style.

Member of the Senior Civil Service
Department of Health

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