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STATUTORY INSTRUMENTS

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**2005 No. 498**

**NATIONAL HEALTH SERVICE,  
ENGLAND AND WALES**

**The National Institute for Clinical  
Excellence (Amendment) Regulations 2005**

<i>Made</i>	- - - -	<i>7th March 2005</i>
<i>Laid before Parliament</i>		<i>10th March 2005</i>
<i>Coming into force</i>	- -	<i>1st April 2005</i>

The Secretary of State for Health, in exercise of the powers conferred by sections 16(4) and 126(4) of, and paragraphs 10, 12 and 16 of Schedule 5 to, the National Health Service Act 1977(1), and of all other powers enabling him in that behalf, hereby makes the following Regulations:

**Citation, commencement, interpretation and application**

1.—(1) These Regulations may be cited as the National Institute for Clinical Excellence (Amendment) Regulations 2005 and shall come into force on 1st April 2005.

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(1) 1977 c. 49; section 16 was substituted by section 65 of, and paragraphs 4 and 9 of Schedule 4 to, the Health Act 1999 (c. 8) (“the 1999 Act”) and amended by sections 1(3) and 6(2) of, and paragraphs 1 and 3 of Schedule 1 and paragraphs 4 and 5 of Schedule 5 to, the National Health Service Reform and Health Care Professions Act 2002 (c. 17) (“the 2002 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”), section 65(1) of, and paragraphs 4 and 37(1) and (6) of Schedule 4 to, the 1999 Act, section 67(1) of, and paragraphs 5(1) and (13)(b) of Schedule 5 to, the Health and Social Care Act 2001 (c. 15) (“the 2001 Act”), sections 6(3)(c) and 37(1) of, and paragraphs 1 and 10(a) 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”); paragraph 10 of Schedule 5 was amended by sections 14 and 15 of, and paragraph 3 of Schedule 6 to, the Health and Social Services and Social Security Adjudications Act 1983 (c. 41), section 54(1) of, and paragraphs 8 and 10 of Schedule 5 to, the Dentists Act 1984 (c. 24), sections 5 and 24 of, and paragraph 14 of Schedule 3 and Part 1 of Schedule 8 to, the Health and Social Security Act 1984 (c. 48), article 7 of S.I. 1985/39, section 1 of, and paragraph 8 of Schedule 1 to, the 1990 Act, sections 2(1) and 5(1) of, and paragraph 60(c) of Schedule 1 and Schedule 3 to, the Health Authorities Act 1995 (c. 17) (“the 1995 Act”), section 65 of, and paragraphs 4, 39(1) and (3) of Schedule 4 and Schedule 5 to, the 1999 Act and section 6 of the 2001 Act; paragraph 12 of Schedule 5 was amended by article 7 of S.I. 1985/39, section 1 of, and paragraph 9 of Schedule 1 to, the 1990 Act, sections 2(1) and 5(1) of, and paragraph 60(e) of Schedule 1 and Schedule 3 to, the 1995 Act and section 65(1) of, and paragraphs 4, 39(1) and (4) of Schedule 4 to, the 1999 Act. See section 128(1), as amended by section 26(2)(g) and (i) of the 1990 Act, for the definitions of “prescribed” and “regulations”. 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, and Schedule 1 to, the National Assembly for Wales (Transfer of Functions) Order 1999, S.I. 1999/672 (“the 1999 Order”); 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 Regulations are made by the Secretary of State in exercise of concurrent powers with the National Assembly for Wales. See article 2(c) of the Transfer Order.

(2) In these Regulations “the principal Regulations” means the National Institute for Clinical Excellence Regulations 1999(2).

(3) These Regulations apply in England.

### **Amendment of regulations 1 of the principal Regulations**

2. Regulation 1 of the principal Regulations (citation, commencement and interpretation) is amended as follows—

(a) the following definitions are inserted in the appropriate alphabetical order—

“the FHSAA” means the Family Health Service Appeal Authority constituted under section 49S of the Act(3);

“national NHS disqualification” means—

- (a) a decision made by the FHSAA under section 49N of the Act(4), or
- (b) a decision by the NHS Tribunal which is treated as a national disqualification by the FHSAA by virtue of regulation 6(4)(b) of the Abolition of the National Health Service Tribunal (Consequential Provisions) Regulations 2001(5) or regulation 6(4)(b) of the Abolition of the National Health Service Tribunal (Consequential Provisions) Regulations 2002(6);

“the NHS Tribunal” means the Tribunal constituted under section 46 of the Act(7) for England and Wales;

“primary care list” means—

- (a) a list referred to in section 49N(1)(a) to (c) of the Act,
- (b) a list of persons undertaking to provide general medical services prepared in accordance with regulations under section 29 of the Act(8) as the list existed on or before 31st March 2004,
- (c) a list of persons approved by a Primary Care Trust for the purpose of assisting in the provision of general medical services prepared in accordance with regulations under section 43D(1) of the Act(9) as the list existed on or before 31st March 2004, or
- (d) a services list referred to in section 8ZA(1)(a) of the National Health Service (Primary Care) Act 1997(10) as the list existed on or before 31st March 2004;”,

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(2) [S.I.1999/260](#) as amended by S.I.s [1999/2218](#), [2002/1759](#) and [2004/596](#).

(3) Section 49S was inserted by section 27(1) of the 2001 Act and amended by section 1(3) of, and paragraphs 1 and 18 of Schedule 1 to, the 2002 Act.

(4) Section 49N was inserted by section 25 of the 2001 Act and amended by section 2(5) of, and paragraphs 1 and 25 of Schedule 2 to, the 2002 Act and section 184 of, and paragraph 24(a) and paragraph 24(b) of Schedule 11 to, the 2003 Act, in respect of paragraph 24(b) on a date to be appointed. A transitional amendment is made to section 49N(1) inserting sub-paragraph (bb) by article 7(4)(i) of the Health and Social Care (Community Health and Standards) Act 2003 Commencement (No. 2) Order 2004 [S.I. 2004/288](#) (C. 12).

(5) [S.I. 2001/3744](#), as modified and amended by [S.I. 2002/2469](#).

(6) [S.I. 2002/1920](#) amended by [S.I. 2004/865](#).

(7) Section 46 was repealed by section 67 of, and paragraph 5 of Schedule 5 and Part 1 of Schedule 6 to, and the 2001 Act; the NHS Tribunal, except for prescribed cases, had effect in relation to England only until 14th December 2001, and in relation to Wales, only until 26th August 2002; see article 2(5) and (6)(b) of [S.I. 2001/3738](#) which sets out the prescribed cases for England, and article 2(2) and (3)(b) of [S.I. 2002/1919](#) which sets out the prescribed cases for Wales.

(8) Section 29 is repealed by section 196 of, and Schedule 14 to, the 2003 Act.

(9) Section 43D was inserted by section 24 of the 2001 Act and amended by section 2(5) of, and paragraphs 1 and 20 of Schedule 2 to, the 2002 Act; section 43D(1) is repealed in part by section 196 of, and Schedule 14 to, the 2003 Act; section 43D(10) (a) (and other parts of 43D(10) on a date to be appointed) is amended by section 184 of, and paragraph 20 of Schedule 11 to, the 2003 Act.

(10) [1997 c. 46](#); section 8ZA was inserted by section 26(2) of the 2001 Act and was amended by section 4(3) of, and paragraphs 1 and 3 of Schedule 3 of the 2002 Act; and is repealed by section 196 of, and Schedule 14 to, the 2003 Act so far as it relates to personal medical services and otherwise on a date to be appointed.

- (b) for the definition of “the Institute” substitute the following definition—
- ““the Institute” means the National Institute for Health and Clinical Excellence established by the Order(11);”,
- (c) for the definition of “health service body” substitute the following definition—
- ““health service body” means—
- (a) a Strategic Health Authority(12), Special Health Authority(13), Primary Care Trust(14), NHS trust(15), Local Health Board(16) or NHS foundation trust(17),
  - (b) a Health Board or Special Health Board constituted under section 2 of the National Health Service (Scotland) Act 1978(18) or the Scottish Dental Practice Board, the Common Service Agency for the Scottish Health Service or an NHS trust constituted under, respectively, sections 4, 10 or 12A of that Act(19),
  - (c) the Dental Practice Board constituted under section 37(1) of the Act(20),
  - (d) the Commission for Health Improvement(21),
  - (e) the Commission for Healthcare Audit and Inspection(22),
  - (f) the Public Health Laboratory Service Board(23),
  - (g) the Health Protection Agency(24);
  - (h) the Secretary of State,
  - (i) the Independent Regulator of NHS Foundation Trusts,
  - (j) the Northern Ireland Central Services Agency for the Health and Social Services established under the Health and Personal Social Services (Northern Ireland) Order 1972(25),

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(11) [S.I. 1999/220](#) as amended by [S.I. 1999/2219,2002/1760](#) and [2005/497](#).

(12) See section 8 of the Act.

(13) See section 11 of the Act.

(14) See section 16A of the Act.

(15) See section 5 of the 1990 Act.

(16) See section 16BA of the Act.

(17) See section 1 of the 2003 Act.

(18) [1978 c. 29](#).

(19) Section 4 was amended by section 12(3) and Schedule 3 of the Health and Medicines Act [1988 \(c. 49\)](#) (“the 1988 Act”); section 10 was amended by paragraph 2 of Schedule 6 to the Health Services Act [1980 \(c. 53\)](#) and Schedule 10 to the 1990 Act; section 12A was inserted by section 31 of the 1990 Act and amended by section 46(1) of the 1999 Act.

(20) Section 37(1) was amended by section 12 of the 1988 Act and repealed in part by section 25 and Schedule 3 of that Act; amended by section 2(1) of, and paragraph 26 of Schedule 1 to, the 1995 Act and section 1(3) of, and paragraphs 1 and 17 of Schedule 1 to, the 2002 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, and Schedule 1 to, the 1999 Order, except that the regulation-making function in section 37(1) continues as a function of the Secretary of State in respect of Wales as well as England; see the entry in Schedule 1 for the National Health Service Act 1977 as amended; the Dental Practice Board is abolished by sections 181 and 196 of, and Schedule 14 to, the 2003 Act on a date to be appointed.

(21) The Commission for Health Improvement was established by section 19 of the 1999 Act and abolished by section 44(1) of the 2003 Act on 1st April 2004.

(22) See section 41 of the 2003 Act for the establishment of the Commission for Healthcare Audit and Inspection.

(23) See section 5(4) and (5) of, and Schedule 3 to, the Act; section 5(4) was amended by section 1 of the Public Health Laboratory Service Act [1979 \(c. 23\)](#). The functions of the Secretary of State under these provisions, so far as exercisable in relation to Wales, except for the functions specified in paragraphs 3, 11, 12 and 16 to 18 of Schedule 3 to the Act relating to the Public Health Laboratory Service Board, are transferred to the National Assembly for Wales by article 2(a) of, and Schedule 1 to, the 1999 Order; see the entry in Schedule 1 for the National Health Service Act 1977 as amended; the Public Health Laboratory Service Board is abolished by section 190 of, and Part 7 of Schedule 14 to, the 2003 Act.

(24) Health Protection Agency Act [2004 \(c. 17\)](#).

(25) [S.I. 1972/1265 \(N.I. 14\)](#).

- (k) a special health and social services agency established under the Health and Personal Social Services (Special Agencies) (Northern Ireland) Order 1990<sup>(26)</sup>,
- (l) a Health and Social Services Board constituted under the Health and Personal Social Services (Northern Ireland) Order 1972,
- (m) a Health and Social Services trust established under the Health and Personal Social Services (Northern Ireland) Order 1991<sup>(27)</sup>, and
- (n) the Department of Health, Social Services and Public Safety for Northern Ireland;”.

#### **Amendment of regulation 4 of the principal Regulations**

**3.** In regulation 4 of the principal Regulations (appointment of chief officers) delete the words “and a clinical director” and insert the words “,a director of clinical and public health and a director of health improvement.”.

#### **Amendment of regulation 5 of the principal Regulations**

**4.** For regulation 5(1) of the principal Regulations (disqualification for appointment) substitute the following paragraph—

“**5.—**(1) Subject to regulation 4 (cessation of disqualification), a person shall be disqualified for appointment as the chairman or as a non-officer member if—

- (a) he has, within the preceding five years, been convicted in the United Kingdom of any offence or convicted elsewhere of an offence which, if committed in any part of the United Kingdom would constitute a criminal offence in that part, and in either case has been sentenced to a period of imprisonment (whether suspended or not) for a period of not less than three months without the option of a fine, and which has not been quashed on appeal;
- (b) he is the subject of a bankruptcy restrictions order or an interim bankruptcy restrictions order;
- (c) he has been dismissed within the previous five years, otherwise than by reason of redundancy, from any paid employment with a health service body;
- (d) he is a person whose tenure of office as the chairman, a member, a director or a governor of a health service body has been terminated on the grounds that—
  - (i) it was not in the interests of, or conducive to the good management of, the health service body or of the health service that he should continue to hold that office,
  - (ii) he failed, without reasonable cause, to attend any meeting of that health service body for three successive meetings, or
  - (iii) he failed to declare a pecuniary interest or withdraw from consideration of any matter in respect of which he had a pecuniary interest;
- (e) he—
  - (i) is the subject of a national NHS disqualification,
  - (ii) was refused nomination or approval to fill a vacancy for a medical practitioner pursuant to regulations made under section 29B(2A) of the Act

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<sup>(26)</sup> S.I. 1990/247 (N.I. 3).

<sup>(27)</sup> S.I. 1991/194 (N.I. 1).

- and was not subsequently nominated or approved or included in a primary care list(28),
- (iii) has been refused admission to a primary care list on grounds corresponding to the conditions referred to in section 49F(2), (3) or (4) of the Act(29) and has not subsequently been included in a primary care list,
  - (iv) is conditionally included in a primary care list(30),
  - (v) has been removed from a primary care list on any of the grounds set out in section 49F(2), (3) or (4) of the Act or by a direction of the NHS Tribunal and has not subsequently been included in such a list,
  - (vi) is contingently removed from a primary care list(31), or
  - (vii) is suspended from a primary care list(32) or treated as so suspended by virtue of regulation 6(2) of the Abolition of the National Health Service Tribunal (Consequential Provisions) Regulations 2001 or regulation 6(2) of the Abolition of the National Health Service Tribunal (Consequential Provisions) Regulations 2002,

and in this sub-paragraph any reference to a provision in the Act includes a reference to the provision corresponding to that provision in legislation relating to Scotland and Northern Ireland;

- (f) he is subject to a disqualification order under the Company Directors Disqualification Act 1986(33), the Companies (Northern Ireland) Order 1986(34) or to an order made under section 429(2)(b) of the Insolvency Act 1986(35) (disabilities on revocation of administration order against an individual);
- (g) he has been—
  - (i) removed from the office of charity trustee or trustee for a charity by an order made by the Charity Commissioners or the High Court on the grounds of any misconduct or mismanagement in the administration of the charity for which he was responsible or to which he was privy, or which he, by his conduct, contributed to or facilitated, or
  - (ii) removed under section 7 of the Law Reform (Miscellaneous Provisions) (Scotland) Act 1990(36) (powers of Court of Session to deal with management of charities) from being concerned in the management or control of any body.”.

### **Amendment of Regulation 6 of the principal Regulations**

5. For regulation 6 of the principal Regulations (cessation of disqualification) substitute the following—

- “6.—(1) Subject to paragraph (2), where a person is disqualified under regulation 5(1) (c) or (g)(i) he may, after the expiry of two years beginning on the date on which he

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(28) Section 29B is repealed by section 196 of, and Schedule 14 to, the 2003 Act.

(29) Section 49F was inserted by section 25 of the 2001 Act and amended by section 2(5) of, and paragraphs 1 and 21(a) of Schedule 2 to, the 2002 Act; section 49F(1)(a) (and 49F(1)(c)) are repealed by section 196 of, and Schedule 14 to, the 2003 Act.

(30) See section 43ZA of the Act for conditional inclusion. See also sections 28X(5) and 43D(4) of the Act and section 8ZA(4) (a) of the 1997 Act.

(31) See section 49G of the Act for contingent removal. See also sections 28X(4) and 43D(6) of the Act.

(32) See section 49I of the Act for suspension. See also sections 28X(4) and 43D(6) of the Act and section 8ZA(7) of the 1997 Act.

(33) 1986 c. 46.

(34) S.I. 1986/1032 (N.I.6).

(35) 1986 c. 45.

(36) 1990 c. 40.

was dismissed or removed, apply in writing to the Secretary of State to remove the disqualification, and the Secretary of State may direct that the disqualification shall cease.

(2) Where the Secretary of State refuses an application to remove a disqualification no further application may be made by that person until the expiry of the period of two years beginning with the date of the application and this paragraph shall apply to any subsequent application.

(3) Where a person is disqualified under regulation 5(1)(d), the disqualification shall cease on the expiry of the period of two years beginning on the date of the termination of his tenure of office or such longer period as the Secretary of State specifies when terminating his period of office but the Secretary of State may, on application being made to him by that person, reduce the period of disqualification.”.

#### **Amendment of regulation 8 of the principal Regulations**

6. Regulation 8 of the principal Regulations (termination of tenure of office of chairman and non-officer members) is amended as follows—

- (a) in regulation 8(5) (b) after the word “appointment” insert the words “or later”;
- (b) in regulation 8(6) after the word “pecuniary” delete the words “or other personal”.

#### **Amendment of regulation 9 of the principal Regulations**

7. In regulation 9 of the principal Regulations (appointment of committees and sub-committees) at the end of regulation 9(5) insert the following paragraph—

“(6) Subject to such directions as may be given by the Secretary of State, regulations 5 and 6 apply to the appointment of members of committees and sub-committees of the Institute appointed under this regulation as they apply to the appointment of members of the Institute.”.

#### **Amendment of regulation 12 of the principal Regulations**

8. In regulation 12 of the principal Regulations (disability of chairman and members in proceedings on account of pecuniary or other personal interest) for the heading and paragraphs (1) – (7) substitute the following—

##### **“Disability of chairman and members in proceedings on account of pecuniary interest**

12.—(1) Subject to the following provisions of this regulation, if the chairman or a member has any pecuniary interest, direct or indirect, in any contract, proposed contract or other matter and is present at any meeting of the Institute to which the contract, proposed contract or other matter is the subject of consideration, he shall at the meeting and as soon as practicable after its commencement, disclose his interest and shall not take part in the consideration or discussion of the contract, proposed contract or other matter or vote on any question with respect to it.

(2) The Secretary of State may, subject to such conditions as he may think fit to impose, remove any disability imposed by this regulation in any case in which it appears to him to be in the interests of the health service that the disability should be removed.

(3) The Institute may, by Standing Orders made under regulation 11(2), provide for the exclusion of the chairman or a member from a meeting of the Institute while any contract, proposed contract or other matter in which he has a pecuniary interest, direct or indirect, is under consideration.

(4) Any remuneration, compensation or allowances payable to the chairman or a member by virtue of paragraph 9 of Schedule 5 to the Act (pay and allowances) shall not be treated as a pecuniary interest for the purpose of this regulation.

(5) Subject to paragraphs (2) and (6), the chairman or member shall be treated for the purpose of this regulation as having an indirect pecuniary interest in a contract, proposed contract or other matter if—

- (a) he, or a nominee of his, is a director of a company or other body, not being a public body, with which the contract was made or is proposed to be made or which has a direct pecuniary interest in the other matter under consideration; or
- (b) he is a partner of, or is in the employment of, a person with whom the contract was made or is proposed to be made or who has a direct pecuniary interest in the other matter under consideration,

and in the case of two persons living together as a couple (whether married or not) the interest of one shall, if known to the other, be deemed for the purpose of this regulation to be also an interest of the other.

(6) Neither the chairman nor a member shall be treated as having a pecuniary interest in any contract, proposed contract or other matter by reason only—

- (a) of his membership of a company or other body if he has no beneficial interest in any securities of that company or other body; or
- (b) of an interest in any company, body or person with which he is connected as mentioned in paragraph (5) which is so remote or insignificant that it cannot reasonably be regarded as likely to influence him in the consideration or discussion of, or voting on, any question with respect to that contract, proposed contract or other matter.

(7) Where the chairman or a member—

- (a) has an indirect pecuniary interest in a contract, proposed contract or other matter by reason only of beneficial interest in securities of a company or other body; and
- (b) the total nominal value of those securities does not exceed £5,000 or one-hundredth of the total nominal value of the issued share capital of the company or body, whichever is the lesser; and
- (c) if the share capital is of more than one class, the total nominal value of shares of any one class in which he has a beneficial interest does not exceed one-hundredth of the total issued share capital of that class,

this regulation shall not prohibit him from taking part in the consideration or discussion of the contract, proposed contract or other matter, or from voting on any question with respect to it without prejudice however to his duty to disclose his interest.”.

Signed by authority of the Secretary of State

7th March 2005

*Warner*  
Parliamentary Under Secretary of State,  
Department of Health

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations amend the National Institute for Clinical Excellence Regulations 1999 (the principal Regulations) which make provision concerning membership and procedure of the National Institute for Clinical Excellence (the Institute) which is a Special Health Authority established under the National Health Service Act 1977.

Regulation 2 makes certain consequential amendments to definitions including an amendment to the definition of “the Institute” consequent on the change of the name of the Institute from the National Institute for Clinical Excellence to the National Institute for Health and Clinical Excellence. Regulation 3 requires the Institute to appoint a director of health improvement and renames the office of clinical director to that of director of clinical and public health.

Regulations 4 and 5 make amendments to the provisions relating to the disqualification for appointment and cessation of disqualification as chairman or a non officer member of the Institute and regulation 7 extends those provisions to the appointment of members of committees and sub committees.

Regulations 6 and 8 amend the provisions relating to the disability of chairman and members in proceedings on account of pecuniary or other personal interest.