STATUTORY INSTRUMENTS

2015 No. 559

NATIONAL HEALTH SERVICE, ENGLAND

The National Health Service (Clinical Negligence Scheme) Regulations 2015

Made - - - -	*4th March 2015*
Laid before Parliament	*11th March 2015*
Coming into force - -	*1st April 2015*

The Secretary of State makes these Regulations in exercise of the powers conferred by sections 71 and 272(7) and (8) of the National Health Service Act 2006(**1**).

In accordance with section 71(1) of that Act, these Regulations are made with the consent of the Treasury.

General

Citation, commencement and application

1.—(1) These Regulations may be cited as the National Health Service (Clinical Negligence Scheme) Regulations 2015.

(2) These Regulations come into force on 1st April 2015.

(3) These Regulations apply to England only.

Interpretation

2.—(1) In these Regulations—

"the 1996 Regulations" means the National Health Service (Clinical Negligence Scheme) Regulations 1996(**2**);

"the 2006 Act" means the National Health Service Act 2006;

(**1**) 2006 c. 41. Section 71 was amended by section 142 of, and paragraph 85 of Schedule 5 and Part 4 of Schedule 15 to, the Health and Social Care Act 2008 (c. 14); by paragraph 18 of Schedule 4, paragraphs 17 and 19 of Schedule 7, paragraphs 1 and 28 of Schedule 14, paragraph 10(1) and (3) of Schedule 17 and paragraph 9(1) and (3) of Schedule 19 to the Health and Social Care Act 2012 ("the 2012 Act"); and by paragraph 24(3) of Schedule 5 and paragraph 18(9) of Schedule 7 to the Care Act 2014 (c. 23). The powers conferred by the National Health Service Act 2006 which are exercised by the Secretary of State in making these Regulations are exercisable only in relation to England by virtue of section 271(1) of that Act.

(**2**) S.I. 1996/251. The Regulations were amended by S.I. 1997/527, 1999/1274, 2000/2341, 2002/1073, 2002/2469, 2004/696, 2005/604, 2006/3087, 2012/1641, 2013/497, 2014/933, 2014/3090 and 2015/137.

"the 2012 Act" means the Health and Social Care Act 2012(**3**);

"the appointed day" means the date on which these Regulations come into force;

"a CCG" means a clinical commissioning group;

"eligible body" means a body specified in sub-paragraphs (a) to (l) of regulation 4(1);

"insolvency" has the meaning given in section 247(1) of the Insolvency Act 1986 (meaning of "insolvency" and "go into liquidation")(**4**);

"membership year", in respect of any eligible body, means any 12 month period starting on 1st April during which the body is a member of the Scheme;

"relevant function" means—

(a) arranging for the provision of services for the purposes of the health service(**5**);

(b) providing services for the purposes of the health service;

(c) exercising functions in relation to the health service;

(d) exercising powers under, or by virtue of, section 7 of the Health and Medicines Act 1988(**6**);

(e) exercising powers under section 13W, 14Z5, 43(3) or 44 of, or paragraphs 19 and 20 of Schedule 4 to, the 2006 Act(**7**);

(f) exercising powers under section 243 or 270 of the 2012 Act; or

(g) exercising powers by virtue of section 240(1)(a) or (b) of the 2012 Act;

"relevant health services"—

(a) means health services provided in England for the purposes of the health service, but

(b) does not include primary care services;

"the Scheme" means the scheme known as the Clinical Negligence Scheme for Trusts(**8**).

(2) In the definition of "relevant health services" in paragraph (1), the reference to "primary care services" is to health services provided under a contract, arrangement or agreement made under or by virtue of any of the following provisions of the 2006 Act—

(a) section 83(2) (primary medical services)(**9**);

(b) section 84(1) (general medical services contracts)(**10**);

(c) section 92 (arrangements by the Board for the provision primary medical services)(**11**);

(d) section 100(1) (general dental services contracts)(**12**);

(**3**) 2012 c. 7.
(**4**) 1986 c.45. Section 247(1) was amended by paragraph 33(1) and (2) of Schedule 17 to the Enterprise Act 2002 (c. 40).
(**5**) "The health service" is defined in section 275 of the National Health Service Act 2006.
(**6**) 1988 c. 49. Section 7 was amended by paragraph 34 of Schedule 9 to the National Health Service and Community Care Act 1990 (c. 19); by section 5 of the Health and Social Care Act 2001 (c. 15); by section 37(2) of the Smoking, Health and Social Care (Scotland) Act 2005 (asp 13); by paragraphs 115 and 116 of Schedule 1 and Schedule 4 to the National Health Service (Consequential Provisions) Act 2006 (c. 43); by paragraph 45 of Schedule 5 to the 2012 Act; and by S.I. 2009/1941.
(**7**) Section 13W was inserted by section 23(1) of the 2012 Act. Section 14Z5 was inserted by section 26 of that Act. Section 43(3) was amended by section 164(2) of that Act. Section 44 was amended by section 165 of that Act. Schedule 4 is repealed by section 179(2) of that Act but, at the date of making these Regulations, no date had been appointed to bring that repeal into force.
(**8**) The Clinical Negligence Scheme for Trusts ("the Scheme") was established by the National Health Service (Clinical Negligence Scheme) Regulations 1996 (S.I.1996/251).
(**9**) Section 83(2) was substituted by paragraph 30(1) and (2) of Schedule 4 to the 2012 Act.
(**10**) Section 84(1) was amended by paragraph 31(1) and (2) of Schedule 4 to the 2012 Act.
(**11**) Section 92 was amended by paragraph 36 of Schedule 4 to the 2012 Act.
(**12**) Section 100(1) was amended by paragraph 43(1) and (2) of Schedule 4 to the 2012 Act.

(e) section 107(1) (arrangements by the Board for the provision of primary dental services)(**13**);

(f) section 115(4) (primary ophthalmic services)(**14**);

(g) section 117(1) (general ophthalmic services contracts)(**15**);

(h) section 126(1) (arrangements for pharmaceutical services)(**16**);

(i) section 127(1) (arrangements for additional pharmaceutical services)(**17**);

(j) section 134 (pilot schemes)(**18**);

(k) Schedule 12 (local pharmaceutical services schemes)(**19**).

The Scheme

Clinical Negligence Scheme for Trusts

3.—(1) The Scheme is to continue to have effect as if it had been established under these Regulations(**20**).

(2) The purpose of the Scheme is to enable eligible bodies to make provision to meet liabilities to which the Scheme applies.

(3) An eligible body may participate in the Scheme only if it is a member of the Scheme.

(4) The Secretary of State will continue to administer the Scheme.

Eligible bodies

4.—(1) The bodies which are eligible to be members of the Scheme are—

(a) the Board;

(b) a CCG;

(c) a Special Health Authority;

(d) the Care Quality Commission;

(e) Health Education England;

(f) the Health Research Authority;

(g) the Health and Social Care Information Centre;

(h) NICE;

(i) an NHS trust;

(**13**) Section 107(1) was substituted by paragraph 48(1) and (2) of Schedule 4 to the 2012 Act.
(**14**) Section 115(4) was substituted by paragraph 54(1) and (4) of Schedule 4 to the 2012 Act.
(**15**) Section 117(1) was amended by paragraph 55(1) and (2) of Schedule 4 to the 2012 Act.
(**16**) Section 126(1) was amended by paragraph 63(1) and (2) of Schedule 4 to the 2012 Act.
(**17**) Section 127(1) was amended by paragraph 64(1) to (3) of Schedule 4 to the 2012 Act.
(**18**) Section 134 was amended by paragraphs 6 and 8 of Schedule 1 to the Health Act 2009 (c. 21) and by paragraph 71 of Schedule 4 to the 2012 Act.
(**19**) Schedule 12 was amended by section 29(1) and (5) to (15) of, and Schedule 6 to, the Health Act 2009; by section 207(12) of, and paragraph 93 of Schedule 4 to, the 2012 Act; and by paragraph 52(1)(b) and (2) of Schedule 9 to the Crime and Courts Act 2013 (c. 22).
(**20**) The Regulations establishing the Scheme (S.I. 1996/251) were made in exercise of powers conferred by section 126(4) of the National Health Service Act 1977 (c. 49) and powers conferred by section 21 of the National Health Service and Community Care Act 1990 (c. 19) ("the 1990 Act"). Section 21 of the 1990 Act was consolidated as section 71 of the National Health Service 2006. By virtue of paragraph 1(2) of Schedule 2 to the National Health Service (Consequential Provisions) Act 2006, anything done under a consolidated provision has effect as if it had been done under the corresponding provision of the consolidating Act. These Regulations are made in exercise of the powers conferred by sections 71 and 272(7) and (8) of the National Health Service Act 2006.

(j) an NHS foundation trust;

(k) a local authority which provides, or arranges the provision of, relevant health services under an arrangement made between the local authority and either—

(i) the Secretary of State; or

(ii) a body specified in sub-paragraph (a) to (c), (i) or (j);

(l) any body ("B") not specified in sub-paragraphs (a) to (k) which provides relevant health services in the circumstances specified in paragraph (2), (3) or (4).

(2) The circumstances specified in this paragraph are where the relevant health services are provided under an arrangement made between B and the Board, a CCG or a Special Health Authority.

(3) The circumstances specified in this paragraph are where the relevant health services—

(a) are provided under an arrangement made between B and another body which is not a member of the Scheme; and

(b) are also the subject of an arrangement made between that other body and the Board, a CCG or a Special Health Authority.

(4) The circumstances specified in this paragraph are where the relevant health services—

(a) are provided under an arrangement made between B and another body which is not a member of the Scheme; and

(b) are also the subject of—

(i) an arrangement made between that other body and a further body which is not a member of the Scheme;

(ii) any further arrangement or arrangements which may have been entered into between bodies which are not members of the Scheme; and

(iii) an arrangement made between the Board, a CCG or a Special Health Authority and a body falling within paragraph (i) or (ii).

Membership of the Scheme

5.—(1) Any eligible body which is a member of the Scheme immediately before the appointed day is to continue to be a member of the Scheme (subject to any cancellation of the membership under regulation 6 (cancellation by a member) or 7 (cancellation by the Secretary of State)(**21**)).

(2) Any eligible body which is not a member of the Scheme may apply to the Secretary of State to become a member of the Scheme.

(3) An application under paragraph (2) must—

(a) be in writing;

(b) be made in such form and submitted in such manner as the Secretary of State may require;

(c) specify a date on which the eligible body proposes that its membership should start; and

(d) contain, or be accompanied by, such information as the Secretary of State may require.

(4) At any time after receiving an application and before determining it, the Secretary of State may in writing require the applicant to provide such further information as the Secretary of State considers necessary for the purposes of determining the application.

(5) Information that may be required under paragraphs (3) and (4) includes—

(**21**) By virtue of regulation 23 of these Regulations, a notice given under the regulation 7 of the National Health Service (Clinical Negligence Scheme) Regulations 1996 (termination of membership) has effect as if given under the corresponding provisions of these Regulations in any case where membership of the Scheme has not ceased by the date on which these Regulations come into force.

(a) the nature of the applicant's relevant functions;

(b) the number of employees of the applicant who are engaged in the performance by the applicant of any relevant function, or any part of such function, which is specified by the Secretary of State;

(c) the qualifications and experience of such employees;

(d) the details of any claim made against the applicant in respect of personal injuries sustained by third parties as a result of the exercise by the applicant of any relevant function; and

(e) such other information as the Secretary of State may request for the purposes of determining the application.

(6) The Secretary of State must—

(a) within 6 weeks of receiving an application made in accordance with requirements under paragraphs (3) and (4), determine whether or not to grant it; and

(b) as soon as reasonably practicable, inform the applicant of the determination by a notice in writing which, if the application is granted, must specify the date on which the applicant's membership is to start.

(7) In determining whether to grant an application, the Secretary of State must have regard to—

(a) the information provided by the applicant; and

(b) such other factors as the Secretary of State considers relevant.

(8) Where an eligible body's application is granted, the body's membership of the Scheme starts on the date specified in the notice under paragraph (6)(b).

Cancellation of membership by a member

6.—(1) This regulation applies only in relation to any member which has been a member of the Scheme for at least 3 consecutive membership years.

(2) The member may cancel its membership of the Scheme by giving the Secretary of State notice in writing of the cancellation.

(3) Where a notice under paragraph (2)—

(a) is given before 1st September in a membership year, the notice takes effect at the end of that membership year;

(b) is given on or after 1st September in a membership year, the notice takes effect at the end of the following membership year.

Cancellation of membership by the Secretary of State

7.—(1) The Secretary of State may cancel a member's membership of the Scheme in any of the circumstances specified in paragraphs (2) to (5).

(2) The circumstances specified in this paragraph are where the member is liable to make a payment to the Secretary of State under regulation 12 (duty of members to make contributions to the Scheme) and that payment remains unpaid for a period of 28 days or more which starts with the date on which the payment becomes due.

(3) The circumstances specified in this paragraph are where the member has failed to provide any information required under regulation 20 (duty of members to provide information)—

(a) before the end of the period of 28 days which starts with the date on which the Secretary of State requests the information; or

(b) if the Secretary of State in writing allows a further period for providing such information, before the end of that further period.