

**2013 No. 497**

**NATIONAL HEALTH SERVICE, ENGLAND**

**The National Health Service (Clinical Negligence Scheme)  
Amendment Regulations 2013**

<i>Made</i>	- - - -	<i>6th March 2013</i>
<i>Laid before Parliament</i>		<i>11th March 2013</i>
<i>Coming into force</i>	- -	<i>1st April 2013</i>

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

These Regulations are made with the consent of the Treasury in accordance with section 71(1) of that Act.

**Citation, commencement, application and interpretation**

1.—(1) These Regulations may be cited as the National Health Service (Clinical Negligence Scheme) Amendment Regulations 2013 and come into force on 1st April 2013.

(2) These Regulations apply to England only.

(3) In these Regulations “the principal Regulations” means the National Health Service (Clinical Negligence Scheme) Regulations 1996(b).

**Amendment of regulation 1 of the principal Regulations**

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

(2) In paragraph (2)—

(a) prior to the definition of “the Act”, insert—

““the 2006 Act” means the National Health Service Act 2006;”;

(b) after the definition of “the Act”, insert—

““CCG” means a clinical commissioning group;”;

(c) after the definition of “an eligible body”, insert—

““first contracting party” means an NHS trust, an NHS foundation trust, a local authority or another body which provides relevant health services, the provision of

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(a) 2006 c.41. Section 71 was amended by sections 95 and 142 of, and paragraph 85 of Schedule 5 to, the Health and Social Care Act 2008 (c.14) and sections 55(1), 56(4), 179(6), 249(1), 277(1) of, and paragraph 18 of Schedule 4 to, paragraphs 17 and 19 of Schedule 7 to, paragraphs 1 and 28 of Schedule 14 to, paragraphs 10(1) and (3) of Schedule 17 to, and paragraphs 9(1) and (3) of Schedule 19 to, the Health and Social Care Act 2012 (c.7).

(b) S.I. 1996/251; amended by S.I. 1997/527, 1999/1274, 2000/2341, 2002/1073, 2002/2469, 2004/696, 2005/604 and 2006/3087.

which is the subject of an arrangement made between it and the Board, a CCG or a Special Health Authority;

“insolvency” has the same meaning as in section 247(1) of the Insolvency Act 1986 (“insolvency” and “go into liquidation”)(a);”;

(d) after the definition of “preceding year”, insert—

““primary care services” means health services provided under a contract, arrangement or agreement made under or by virtue of the following sections of the 2006 Act—

(a) section 83(2) (arrangements by the Board for the provision of primary medical services);

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

(c) section 92 (other arrangements for primary medical services);

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

(e) section 107(1) (other arrangements for the provision of primary dental services);

(f) section 115(4) (power of the Board to make arrangements for the provision of primary ophthalmic services);

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

(h) section 126(1) (pharmaceutical services);

(i) section 127(1) (additional pharmaceutical services);

(j) section 134 (pilot schemes); or

(k) Schedule 12 (local pharmaceutical services schemes);

“primary provider body” means a body described in sub-paragraph (i) of regulation 3(1);”;

(e) for the definition of “relevant function”, substitute—

““relevant function” means the function of arranging for the provision of, or providing, services for the purposes of the health service;”;

(f) after the definition of “relevant function”, insert—

““relevant health services” means health services provided in England for the purposes of the health service, except primary care services;”;

and

(g) after the definition of “the Scheme”, insert—

““sub-provider body” means a body described in sub-paragraph (j) of regulation 3(1);”.

### **Amendment of regulation 3 of the principal Regulations**

3.—(1) Regulation 3 of the principal Regulations (eligible bodies) is amended as follows.

(2) In paragraph (1)—

(a) omit sub-paragraphs (b) and (d); and

(b) after sub-paragraph (e), insert the following sub-paragraphs—

“(f) NICE(b);

(g) the Health and Social Care Information Centre(c);

(h) a local authority which provides, or arranges the provision of, relevant health services, the provision of which is the subject of an arrangement made with the Secretary of State, the Board, a CCG, a Special Health Authority, an NHS trust or an NHS foundation trust;

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(a) 1986 c.45. Section 247(1) was amended by section 248(3) of, and paragraphs 9 and 33(1) and (2) of Schedule 17 to, the Enterprise Act 2002 (c.40).

(b) Established by section 232(1) of the Health and Social Care Act 2012 (c.7).

(c) Established by section 252(1) of the Health and Social Care Act 2012.

- (i) a body (A) (other than a body mentioned in sub-paragraphs (a) to (h)) which provides relevant health services, the provision of which is the subject of a direct arrangement made between it and the Board, a CCG or a Special Health Authority;
- (j) where paragraph (3) applies, a body (B) (other than a body mentioned in sub-paragraphs (a) to (h)) which provides relevant health services, the provision of which is the subject of an arrangement as mentioned in sub-paragraph (i) and a further arrangement between A and B;
- (k) where paragraph (4) applies, a body (C) (other than a body mentioned in sub-paragraphs (a) to (h)) which provides relevant health services, the provision of which is the subject of an arrangement as mentioned in sub-paragraph (i), a further arrangement between A and B as mentioned in sub-paragraph (j), and then a further arrangement between B and C; or
- (l) a person who—
  - (i) immediately before 1st April 2013, is a person specified in paragraph (6) of regulation 4; and
  - (ii) continues to provide the services referred to in paragraph (6)(a) of regulation 4,
 as that regulation appeared prior to these Regulations coming into force.”.

(3) After paragraph (2), insert the following paragraphs—

“(3) This paragraph applies where the primary provider body with which the sub-provider body has made a further arrangement as set out in paragraph (1)(j) is not itself a member of the Scheme (that is, B is only eligible to be a member of the Scheme if A, in respect of the arrangements in question, is not a member).

(4) This paragraph applies where neither the primary provider body nor the sub-provider body with which arrangements are made as mentioned in paragraph (1)(k) are themselves members of the Scheme (that is, C is only eligible to be a member of the Scheme if A and B, in respect of the arrangements in question, are not members).”.

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

**4. In regulation 4 of the principal Regulations (liabilities to which the Scheme applies)—**

(a) after paragraph (1), insert—

“(1A) But where the member is a body mentioned in regulation 3(1)(i), (j) or (k), the Scheme only applies if the liability is in consequence of the arrangements by means of which the body is eligible to be a member.”;

(b) in paragraph (3), for “person” substitute “body”; and

(c) for paragraphs (5) to (9), substitute the following—

“(5) The act or omission referred to in paragraph (4) is an act or omission to act in connection with the provision of services for the purposes of the health service on the part of X or a person employed or engaged by X where the services are provided pursuant to an arrangement by means of which a body can be eligible to be a member.

(6) X is a body which is—

- (a) an NHS trust, an NHS foundation trust, a local authority or another body which provides relevant health services, the provision of which by it (X1) is the subject indirectly of an arrangement made by the Board, a CCG or a Special Health Authority with another provider (that other provider being a first contracting party); or
- (b) a primary provider body (X2) whose membership of the Scheme has terminated in accordance with regulation 7(4)(a).

(7) For the purposes of the Scheme and these Regulations, the liabilities of a first contracting party which is a member are to be taken to include the liabilities referred to in

paragraph (3) of an X1 with which that first contracting party has made arrangements (either directly or indirectly) for the provision of relevant health services and references in these Regulations to the liabilities of a member or eligible body are to be construed accordingly.

(8) For the purposes of the Scheme and these Regulations, the liabilities of the Board, a CCG or a Special Health Authority are to be taken to include the liabilities referred to in paragraph (3) of an X2 with which the Board, the CCG or the Special Health Authority had made arrangements for the provision of relevant health services, during the provision of which the liabilities referred to in paragraph (3) arose, where—

- (a) such liabilities are incurred prior to the date on which that body's membership of the Scheme terminated; and
- (b) such liabilities fall to be met after the date on which that body's membership of the Scheme terminated,

and references in these Regulations to the liabilities of a member or eligible body are to be construed accordingly.”.

#### **Amendment of regulation 7 of the principal Regulations**

**5.**—(1) Regulation 7 of the principal Regulations (termination of membership) is amended as follows.

(2) In paragraph (1) for “12” substitute “7”.

(3) After paragraph (3), insert the following paragraph—

“(4) Where a member which is a primary provider body or a sub-provider body—

- (a) enters into insolvency; or
- (b) is no longer an eligible body,

the Secretary of State may terminate that member's participation in the Scheme with immediate effect.”.

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

**6.**—(1) Regulation 8 of the principal Regulations (members' contributions to the Scheme) is amended as follows.

(2) In paragraph (2)—

- (a) for “the Secretary of State shall have regard to”, substitute “the Secretary of State may have regard to”; and
- (b) after sub-paragraph (c), insert the following sub-paragraph—

“(ca) any agreement between the Secretary of State and the member under regulation 9(1A);”.

(3) In paragraph (3)(d), for “31st October” substitute “31st December”.

(4) For paragraph (6)(d), substitute—

“(d) in relation to any subsequent membership year, at such time, or in such instalments at such times, and in such manner—

- (i) as the Secretary of State and the member may, by no later than 1st March immediately preceding the membership year in question, agree, or
- (ii) in default of such agreement by that date, as the Secretary of State may determine.”.

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

**7.**—(1) Regulation 9 of the principal Regulations (payments under the Scheme) is amended as follows.

(2) In paragraph (1), for “paragraph (2)” substitute “paragraphs (2) and (2A)”.

(3) After paragraph (1), insert the following paragraph—

“(1A) Where a payment falls to be made by any body which has at any time been a member of the Scheme in connection with a claim in respect of a qualifying liability which relates to a breach of the duty of care by that body whilst it was a member and, prior to the date of the termination of that member’s participation in the Scheme—

- (a) the Secretary of State has agreed with the member that the member is to pay an amount under regulation 8(1) in respect of the membership year immediately preceding the date of the termination of the member’s participation in the Scheme determined by the Secretary of State to be sufficient to cover any qualifying liabilities which relate to a breach of the duty of care by the member during any membership year, but which fall to be met after the date of the termination of the member’s participation in the Scheme; and
- (b) the member has, prior to the date of the termination of the member’s participation in the Scheme, either—
  - (i) paid the amount referred to in paragraph (a); or
  - (ii) entered into an agreement with the Secretary of State to pay that amount in instalments after that date,

the Secretary of State may, subject to paragraph (2A), pay to or on behalf of that body an amount to be determined by the Secretary of State in accordance with paragraph (3).”.

(4) Re-number paragraph (2)(d) as paragraph (2A), and at the start of that paragraph prior to “except to such extent” insert “No payment is to be made under paragraphs (1) or (1A)”.

(5) After paragraph (5) insert—

“(6) In paragraphs (2A) and (3), “member” includes a body whose participation in the Scheme has terminated and which falls within paragraph (1A).”.

Signed by authority of the Secretary of State for Health.

*Daniel Poulter*  
Parliamentary Under-Secretary of State,  
Department of Health

5th March 2013

We consent

*Robert Goodwill*  
*Anne Milton*

6th March 2013

Two of the Lords Commissioners of Her Majesty’s Treasury

## EXPLANATORY NOTE

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

These Regulations amend the National Health Service (Clinical Negligence Scheme) Regulations 1996 (“the principal Regulations”) which established a Scheme whereby certain NHS bodies and other bodies providing NHS services may make provision for meeting liabilities to third parties in connection with personal injury arising out of negligence in the carrying out of their functions.

Regulation 3 amends the principal Regulations to enable a number of additional bodies to be eligible to participate in the Scheme. These are NICE; the Health and Social Care Information Centre; local authorities which provide, or arrange the provision of, NHS services (other than primary care services) pursuant to arrangements made with the NHS Commissioning Board, a clinical commissioning group or a Special Health Authority; persons who immediately before 1st April 2013 would have been persons to whom regulation 4(6) of the principal Regulations as they

appeared prior to these Regulations coming into force applied (and so whose liabilities would have been treated as those of the Primary Care Trust which had engaged them to provide services that the PCT had previously provided itself) and who continue to be such persons; bodies (which are not otherwise eligible to participate in the Scheme) which provide NHS services (other than primary care services) pursuant to arrangements made with the NHS Commissioning Board, a clinical commissioning group or a Special Health Authority, whether those arrangements are made directly by that body as a primary contractor, or indirectly as a sub-contractor. However, in the case of sub-contractors, they will only be eligible to participate in the Scheme if the bodies with whom they contract are not themselves members of the Scheme.

Regulation 4 amends the principal Regulations to include as liabilities to which the Scheme applies certain additional liabilities incurred by sub-contractors which provide NHS services (other than primary care services) and certain additional liabilities incurred by certain bodies whose membership of the Scheme has been terminated as a result of insolvency. In particular it is provided that, for the purposes of the Scheme:

- certain liabilities of an NHS trust, an NHS foundation trust, a local authority or another body which provides NHS services (other than primary care services) pursuant to arrangements made indirectly (as a sub-contractor) with the NHS Commissioning Board, a clinical commissioning group or a Special Health Authority are to be treated as the liabilities of the main contractor with whom those arrangements are made by the NHS Commissioning Board, a clinical commissioning group or Special Health Authority; and
- certain liabilities of certain non-NHS bodies which provide NHS services (other than primary care services) pursuant to arrangements made directly with the NHS Commissioning Board, a clinical commissioning group or a Special Health Authority, and whose membership of the Scheme is terminated as a result of insolvency, are to be treated as the liabilities of whichever of the NHS Commissioning Board, a clinical commissioning group or Special Health Authority it made those arrangements with.

Regulation 5 amends the principal Regulations to enable the Secretary of State to terminate the membership of the Scheme of a member which is a non-NHS body and provides NHS services under arrangements made with the NHS Commissioning Board, a clinical commissioning group or a Special Health Authority with immediate effect if that member becomes insolvent or the member is no longer an eligible body. It also enables a member to terminate its membership of the Scheme by means of 7 months rather than 12 months' written notice.

Regulation 6 amends the principal Regulations to change some of the deadlines by which notifications of payments must be made, and by which payments must be made, under the Scheme.

Regulations 6 and 7 amend the principal Regulations to enable the Secretary of State to agree with a member that that member can make a payment (or make future payments in instalments) prior to terminating its membership of the Scheme determined by the Secretary of State to be sufficient to cover liabilities which have been incurred prior to its membership terminating but have not yet fallen to be met. If there is such an agreement, and payment is also made or agreed to be made, then the Secretary of State may make payments out of the Scheme to cover any liabilities of that ex-member which fall to be met after its membership has terminated providing the other relevant conditions for payment in regulation 9 of the principal Regulations are met.



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STATUTORY INSTRUMENTS

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