#### STATUTORY INSTRUMENTS

## 1996 No. 251

# NATIONAL HEALTH SERVICE, ENGLAND AND WALES

The National Health Service (Clinical Negligence Scheme) Regulations 1996

Made - - - - 7th February 1996
Laid before Parliament 8th February 1996
Coming into force - - 1st March 1996

The Secretary of State for Health, in exercise of powers conferred by section 126(4) of the National Health Service Act 1977(1) and section 21 of the National Health Service and Community Care Act 1990(2) and of all other powers enabling him in that behalf, and with the consent of the Treasury, hereby makes the following Regulations:

#### Citation, commencement and interpretation

- **1.**—(1) These Regulations may be cited as the National Health Service (Clinical Negligence Scheme) Regulations 1996, and shall come into force on 1st March 1996.
  - (2) In these Regulations, unless the context otherwise requires—
    - "the Act" means the National Health Service and Community Care Act 1990;
    - "an eligible body" means a body of a kind described in regulation 3;
    - "member" means an eligible body which is a member of the Scheme;
    - "membership year" means, in relation to an eligible body, any period of 12 months beginning on 1st April during any part of which that body is a member of the Scheme;
    - "preceding year" means, in relation to a membership year, the period of 12 months immediately preceding that membership year;
    - "qualifying liability" means a liability of a kind described in regulation 4;
    - "relevant function" means a function of the kind described in regulation 3(1);
    - "the Scheme" means the Clinical Negligence Scheme for Trusts established by regulation 2.

<sup>(1) 1977</sup> c. 49 ("the 1977 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").

<sup>(2) 1990</sup> c. 19; see, for the definition of "regulations", section 128(1) of the 1977 Act, as amended by section 26(2) (i) of the 1990 Act. See also paragraph 79(a) of Schedule 1 to the Health Authorities Act 1995 (c. 17).

(3) In these Regulations, a reference to a numbered regulation is a reference to the regulation which bears that number in these Regulations, and a reference in a regulation to a numbered paragraph is a reference to the paragraph which bears that number in that regulation.

#### **Establishment of scheme**

**2.** There is hereby established a scheme, to be known as the Clinical Negligence Scheme for Trusts, whereby an eligible body may, in accordance with the following provisions of these Regulations, make provision to meet qualifying liabilities.

## Eligible bodies

- 3.—(1) A body is eligible to participate in the Scheme if it is—
  - (a) a National Health Service trust,
  - (b) a Health Authority whose area is situated in England, or
  - (c) a Special Health Authority,

whose functions include the function of managing for the purposes of the health service any hospital or other establishment or facility situated in England at or from which services are provided under the National Health Service Act 1977.

(2) Until 1st April 1996, paragraph (1)(b) shall have effect as if the reference to a Health Authority whose area is situated in England were a reference to a Regional Health Authority and to any District Health Authority whose district is situated in England.

## Liabilities to which the Scheme applies

**4.** The Scheme applies to any liability in tort owed by a member to a third party in respect of or consequent upon personal injury or loss arising out of or in connection with any breach of a duty of care owed by that body to any person in connection with the diagnosis of any illness, or the care or treatment of any patient, in consequence of any act or omission to act on the part of a person employed or engaged by a member in connection with any relevant function of that member.

### Administration of the Scheme

**5.** The Scheme shall be administered by the Secretary of State.

## Membership of the Scheme

- **6.**—(1) An eligible body which, before 1st December 1995, gave notice in writing to the Secretary of State of its wish to participate in a scheme under section 21 of the Act during any period beginning before 1st April 1996 shall be a member of the Scheme with effect from 1st March 1996.
- (2) An eligible body which, before 1st February 1996, gave notice in writing of its wish to participate in such a scheme with effect from 1st April 1996 shall be a member of the Scheme with effect from that date.
- (3) An eligible body to which neither paragraph (1) nor paragraph (2) applies which wishes to participate in the Scheme during any period beginning after 31st March 1997 shall apply to the Secretary of State to be admitted as a member.
  - (4) An application under paragraph (3) shall—
    - (a) be made in writing in such form as the Secretary of State may require; and
    - (b) be made no later than 1st October in the calendar year preceding that in which the eligible body wishes its first membership year to begin.

- (5) An applicant shall provide such information as the Secretary of State may in writing request it to provide, as respects—
  - (a) the nature of its relevant functions;
  - (b) the number of employees of the applicant who are engaged in its performance of any relevant function, or such part of any relevant function as the Secretary of State may specify, and the qualifications and experience of those employees;
  - (c) the nature and extent of any claims made against the applicant in respect of personal injuries sustained by third parties as a result of the carrying out by the applicant of any relevant function; and
  - (d) such other information as he may request in connection with the application.
- (6) The Secretary of State shall, having regard to the information provided by the applicant under this regulation, and to such other factors as he considers to be material to the application, determine whether or not the applicant should be admitted as a member, and shall notify the applicant of his decision in writing.
- (7) Where the application of an eligible body has been successful, that body shall be admitted as a member with effect from the beginning of the membership year next following the Secretary of State's decision.
- (8) In this regulation "applicant" means an eligible body which has applied under paragraph (3) to be admitted as a member, and "application" shall be construed accordingly.

## **Termination of membership**

- 7.—(1) Subject to paragraph (2), a member may terminate its participation in the Scheme on 31st March in any year by giving not less than 12 months' notice in writing to that effect to the Secretary of State.
- (2) A member's participation in the Scheme may not be terminated, by notice under paragraph (1)
  - (a) where its membership takes effect on 1st March 1996, before 31st March 1998;
  - (b) where its membership takes effect on 1st April 1996, before 31st March 1999; and
  - (c) in any other case, before the expiry of three consecutive membership years beginning on the date on which, by virtue of regulation 6(7), its membership takes effect.
  - (3) Where—
    - (a) any payment which a member is, by virtue of regulation 8 (contributions under the Scheme), liable to make to the Secretary of State has remained unpaid for a period of not less than 28 days beginning on the date on which the payment should have been made;
    - (b) a member has failed to provide, within 28 days, or such further period as the Secretary of State may in writing allow, of being requested to do so, any information which it is required by virtue of regulation 10 (provision of information) to provide; or
    - (c) the continued membership of any member would, in the opinion of the Secretary of State, be detrimental to the efficient administration of the Scheme or to the interests of other members,

the Secretary of State may give notice in writing to that member that its participation in the Scheme is to cease on a date falling not less than 28 days after that on which the notice is given, and that member's participation in the Scheme shall, unless the Secretary of State in writing withdraws the notice before that date, be terminated on that date.

#### Members' contributions to the Scheme

- **8.**—(1) A member shall pay to the Secretary of State in respect of each membership year such amount as shall be determined in relation to that member, and notified to it, in accordance with this regulation.
- (2) When determining in relation to any member the amount of the payment to be made under paragraph (1), the Secretary of State shall have regard to—
  - (a) his estimate of the total amount which will, by virtue of regulation 9 (payments under the Scheme), fall to be paid during that membership year in respect of all qualifying liabilities under the Scheme;
  - (b) the nature of the member's relevant functions;
  - (c) the number of employees of the member who are engaged in its performance of a relevant function, or any part of such a function, and the qualifications and experience of those employees;
  - (d) any agreement between the Secretary of State and the member that regulation 9(2)(b) or (c) is not to apply in relation to certain liabilities incurred by the member; and
  - (e) his assessment of—
    - (i) the likely effectiveness of any steps being taken, or to be taken, by the member, as respects the manner in which it exercises any relevant function, with a view to reducing the incidence of qualifying liabilities in connection with that function, and
    - (ii) the effectiveness of any such steps which may previously have been taken;

and may have regard to any other factor concerning that or any other member or the Scheme which he considers to be material to his determination.

- (3) The Secretary of State shall give notice in writing to each member—
  - (a) as respects any period before 1st April 1996, by no later than 14th March 1996;
  - (b) as respects the membership year beginning on 1st April 1996, by no later than 31st March 1996; and
- (c) as respects any other membership year, by no later than 31st October in the preceding year; of the amount of the payment which it is to make under paragraph (1).
- (4) Where, after notice has been given to a member in accordance with paragraph (3) in relation to any membership year which begins after 31st March 1996, it appears to the Secretary of State that—
  - (a) the amount specified in the notice was—
    - (i) incorrectly calculated, or
    - (ii) determined by reference to information which was incorrect; or
  - (b) in the light of further information which has become available to him, the determination of that amount ought to be reconsidered,

he shall reconsider the determination and may, at any time before the end of the membership year to which it relates, revise the amount of the payment to be made under paragraph (1).

- (5) Where an amount is revised under paragraph (4), the Secretary of State shall give to the member notice in writing of the revised amount, and that paragraph shall have effect in relation to that amount as if the notice had been given under paragraph (3).
- (6) Any amount which falls to be paid by a member under paragraph (1) shall be paid by the member to the Secretary of State—
  - (a) in relation to any period before 1st April 1996, by no later than 31st March 1996;

- (b) in relation to the membership year beginning on 1st April 1996, by 30th April 1996 or by such later date as the Secretary of State may allow; and
- (c) in relation to any other 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 January immediately preceding the membership year in question, agree; or
  - (ii) in default of such agreement by that date, as the Secretary of State shall determine.

### Payments under the Scheme

- **9.**—(1) Where, in any membership year, a qualifying liability falls to be met by any member, the Secretary of State may, subject to paragraph (2), pay to that member an amount to be determined by him in accordance with paragraph (3).
  - (2) No payment shall be made under paragraph (1)—
    - (a) in respect of any liability which falls to be met after a member has given notice under regulation 7(1) to terminate its participation in the Scheme, unless the Secretary of State is satisfied that the liability would have fallen to be met at that time irrespective of the member's decision to give such notice;
    - (b) in respect of any liability incurred by an eligible body before the beginning of its first membership year, unless—
      - (i) the claim by a third party against the member in respect of that liability was made after the beginning of the first membership year,
      - (ii) the Secretary of State is satisfied that the member informed him, by no later than the qualifying date, that the claim had been made,
      - (iii) the Secretary of State agreed, no later than the beginning of the first membership year, that this sub-paragraph shall not apply so as to preclude a payment under paragraph (1) in respect of any claim in relation to which heads (i) and (ii) above are satisfied, and
      - (iv) that agreement remains in force at the date on which the claim falls to be met by the member;
    - (c) in respect of any liability which falls to be met after the date of the termination of the member's participation in the Scheme, unless—
      - (i) the claim by a third party against the member in respect of that liability was made prior to that date,
      - (ii) the Secretary of State is satisfied that the member informed him, by no later than the qualifying date, that the claim had been made,
      - (iii) prior to the date of termination of the member's participation in the Scheme, the Secretary of State agreed that this sub-paragraph shall not apply so as to preclude a payment under paragraph (1) in respect of any claim in relation to which heads (i) and (ii) above are satisfied, and
      - (iv) that agreement remained in force at the date of termination;
    - (d) except to such extent as the Secretary of State may determine, in respect of—
      - (i) any liability admitted by a member without the prior consent in writing of the Secretary of State,
      - (ii) any liability determined by a Court in proceedings conducted by the member otherwise than in consultation with the Secretary of State,

- (iii) any payment which the member has agreed to make otherwise than in the course of legal proceedings, or in consequence of its having compromised legal proceedings, without the prior consent in writing of the Secretary of State, or
- (iv) any liability of an amount which is less than that for the time being agreed between the Secretary of State and the member as the minimum amount of any liability in respect of which a payment is to be made under the Scheme.
- (3) The amount of any payment to a member under paragraph (1) shall be determined by reference to—
  - (a) where an award of damages has been made against the member by a Court, the amount of that award, together with the amounts of the legal and associated costs awarded to the plaintiff and of any such costs incurred by the member;
  - (b) where legal proceedings have been compromised by the member, the amount of—
    - (i) any sum paid by the member in relation to the plaintiff's claim for damages,
    - (iii) the member's contribution towards any legal and associated costs incurred by the plaintiff, and
    - (iii) any such costs incurred by the member;
  - (c) where, in any legal proceedings, a Court has declined to award damages against the member, the amount of any legal and associated costs incurred by the member, to the extent that such costs are not recoverable from the plaintiff or from the Legal Aid Board under section 18 of the Legal Aid Act 1988(3);
  - (d) where the member has agreed to make a payment, otherwise than in the course of legal proceedings, in settlement of the plaintiff's claim, the amount of that payment.
  - (4) In this regulation—
    - (a) "first membership year" means any membership year immediately following any period during which the elegible body was not a member;
    - (b) "member" includes an eligible body whose participation in the Scheme has been terminated and in respect of whom the conditions specified in paragraph (2)(c)(iii) and (iv) are satisfied; and
    - (c) "qualifying date" means the date falling 14 days after that on which the member became aware that a claim had been made, or after that on which, in the opinion of the Secretary of State, the member ought to have become aware of that fact, whichever is the later.

## **Provision of information**

- **10.** A member shall, at such times and in such manner as the Secretary of State may require, furnish to the Secretary of State such information as he may request, about—
  - (a) the nature of any relevant function being carried on, or to be carried on, by the member in any membership year which the Secretary of State may specify;
  - (b) the number of employees of the member who are engaged in its performance of any relevant function, or such part of any relevant function as the Secretary of State may specify, and the qualifications and experience of those employees; and
  - (c) any event of which the member is aware which it considers might give rise to a qualifying liability.

## Availability of directions and guidance

- 11. The Secretary of State shall make available to eligible bodies, in such form and at such times as he may consider appropriate—
  - (a) any directions(4) he may give, to any body directed under section 21(4)(b) of the Act(5) to carry out functions in connection with the administration of the Scheme, with respect to the discharge by that body of those functions;
  - (b) any guidance he may give to that body as to the manner in which the Scheme is to be administered.

Signed by authority of the Secretary of State for Health

6th February 1996

Gerald Malone Minister of State, Department of Health

We consent,

Michael Bates
Liam Fox
Two of the Lords Commissioners of Her
Majesty's Treasury

7th February 1996

<sup>(4)</sup> See section 17 of the National Health Service Act 1977 (c. 49), as substituted by paragraph 2 of Schedule 3 to the Health and Social Security Act 1984 (c. 48) and amended by sections 3(4) and 12(2) of the National Health Service and Community Care Act 1990 (c. 19); see also paragraph 8 of Schedule 1 to the Health Authorities Act 1995 (c. 17).

<sup>(5)</sup> SeeS.I. 1995/280D.

#### **EXPLANATORY NOTE**

(This note is not part of the Regulations)

These Regulations establish a Scheme (to be known as the "Clinical Negligence Scheme for Trusts") whereby NHS trusts and certain other bodies providing services under the National Health Service Act 1977 may make provision for meeting liabilities to third parties in connection with personal injury arising out of negligence in the carrying out of the bodies' functions (regulations 2, 3 and 4).

The Scheme is to be administered by the Secretary of State (regulation 5). Provision is also made for the admission of bodies to, and their withdrawal and expulsion from, the Scheme (regulations 6 and 7), for payments by bodies, and by the Secretary of State, under the Scheme (regulations 8 and 9) and for the provision of information by bodies to the Secretary of State for the purposes of the Scheme (regulation 10).