
STATUTORY INSTRUMENTS

2019 No. 334

NATIONAL HEALTH SERVICE, ENGLAND

**The National Health Service (Clinical Negligence
Scheme for General Practice) Regulations 2019**

<i>Made</i>	- - - -	<i>20th February 2019</i>
<i>Laid before Parliament</i>		<i>25th February 2019</i>
<i>Coming into force</i>	- -	<i>1st April 2019</i>

The Secretary of State makes these Regulations in exercise of the powers conferred by sections 71 (1) to (3) 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.

Citation, commencement and application

1.—(1) These Regulations may be cited as the National Health Service (Clinical Negligence Scheme for General Practice) Regulations 2019 and come into force on 1st April 2019.

(2) These Regulations apply only in relation to services provided as part of the health service in England.

Interpretation

2.—(1) In these Regulations—

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

“ancillary health services”, subject to paragraph (2)(a), means services, other than primary medical services, provided as part of the health service by—

- (a) a Part 4 contractor whose principal activity consists of the provision of primary medical services;
- (b) a primary medical services sub-contractor whose principal activity consists of the provision of primary medical services; or

(1) [2006 c.41](#). Section 71 of the National Health Service Act 2006 (“2006 Act”) 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 \(c. 14\)](#); 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 (“2012 Act”); and paragraph 24(3) of Schedule 5 and paragraph 18(9) of Schedule 7 to the Care Act [2014 \(c. 23\)](#). By virtue of section 271(1) of the 2006 Act, the powers exercised by the Secretary of State in making these Regulations are exercisable only in relation to England.

(c) a person (“P”) with whom a person specified in paragraph (a) or (b) has made arrangements for P to provide the ancillary health services;

“eligible person” means a person specified in regulation 4;

“health service” means the health service continued under section 1(1) of the 2006 Act;

“Part 4 contractor” means a person providing, or arranging for the provision of, primary medical services in accordance with a contractual arrangement made with that person under one of the specified sections in Part 4 of the 2006 Act;

“primary medical services” means the primary medical services that, pursuant to section 83 of the 2006 Act, the Board(2) is under a duty to secure and which are provided in accordance with a contractual arrangement or agreement (including any such contractual arrangement or agreement that is part of a set of arrangements for the provision of services, in addition to the primary medical services) that is—

(a) made or entered into under one of the specified sections in Part 4 of the 2006 Act; or

(b) made between a Part 4 contractor and a primary medical services sub-contractor;

“primary medical services sub-contractor” means a person providing primary medical services under a contractual arrangement made with a Part 4 contractor;

“relevant function” means—

(a) making arrangements for the provision of primary medical services;

(b) providing primary medical services;

(c) making arrangements for the provision of ancillary health services;

(d) providing ancillary health services;

(e) carrying out an activity in connection with any of the activities in paragraphs (a) to (d);

“relevant liability” means a liability falling within regulation 5;

“Scheme” means the scheme established under regulation 3(1).

(2) In paragraph (1),—

(a) in the definition of “ancillary health services”, unless determined otherwise by the Secretary of State, a person specified in paragraphs (a) to (c) of that definition excludes a subsidiary company; and

(b) “specified sections in Part 4 of the 2006 Act” means the following sections of the 2006 Act—

(i) section 83(2)(3) (primary medical services);

(ii) section 84(1)(4) (general medical services contracts); and

(iii) section 92(1)(5) (arrangements by the Board for the provision of primary medical services).

(3) For the purposes of paragraph (2)(a)—

(2) The Board is defined in section 275(1) of the National Health Service Act 2006 (“2006 Act”) as the National Health Service Commissioning Board. It was established by section 1H of the 2006 Act which was inserted into the 2006 Act by section 9(1) of the Health and Social Care Act 2012 (c.7). The Board has re-branded itself as “NHS England”.

(3) Sections 83(1), (2) and (2A) of the National Health Service Act 2006 were substituted for sections 83(1) and (2) as originally enacted by the Health and Social Care Act 2012 (c.7) section 55(1), Schedule 4, Part 4, paragraphs 30(1) and (2).

(4) Section 84(1) was amended by the Health and Social Care Act 2012, section 55(1), Schedule 4, Part 4, paragraphs 31(1) and (2).

(5) Section 92(1) was substituted by the Health and Social Care Act 2012, section 55(1), Schedule 4, Part 4, paragraphs 31(1) and (2).

- (a) “subsidiary” has the same meaning as in section 1159(1) of the Companies Act 2006⁽⁶⁾; and
- (b) “company” has the same meaning as in subsection (4) of that section.

Establishment, purpose and administration of scheme

3.—(1) A scheme, to be known as the Clinical Negligence Scheme for General Practice, is established.

(2) The purpose of the Scheme is to enable the Secretary of State to make provision to meet relevant liabilities of eligible persons.

(3) The Scheme is to be administered by the Secretary of State.

Eligible persons

4.—(1) An eligible person is a person who is, or who, on the relevant date, was—

- (a) a Part 4 contractor;
- (b) a primary medical services sub-contractor; or
- (c) a person with whom a Part 4 contractor or a primary medical services sub-contractor has made arrangements for that person to provide ancillary health services.

(2) For the purposes of paragraph (1),—

- (a) “relevant date” means the date on which a breach of a duty of care, as mentioned in regulation 5(1), occurred; and
- (b) “arrangements” in sub-paragraph (c) excludes arrangements made under a contract of employment.

Liabilities to which the Scheme applies and exclusions

5.—(1) The Scheme applies to any liability in tort under the law of England and Wales that arises as a consequence of a breach of a duty of care owed by an eligible person to a third party in connection with a relevant function where—

- (a) an act, or an omission to act, on the part of the eligible person, or any other person specified in paragraph (2), results in personal injury or loss to the third party;
- (b) the act, or omission to act, is in connection with the diagnosis of an illness or the provision of care or treatment to the third party; and
- (c) the act, or omission to act, occurs on or after 1st April 2019.

(2) The persons specified for the purposes of paragraph 5(1)(a) are—

- (a) an employee of the eligible person; or
- (b) any other individual who is otherwise engaged, or permitted, by the eligible person to carry out an activity connected to a relevant function.

(3) Where a liability of an eligible person is a liability to which both paragraph (1) and regulation 8(1) (liabilities to members) of the National Health Service (Clinical Negligence Scheme) Regulations 2015⁽⁷⁾ (“CNST Regulations”) apply, the Secretary of State must determine whether the liability is to be met under this Scheme or the scheme under the CNST Regulations.

⁽⁶⁾ 2006 c. 46.

⁽⁷⁾ S.I. 2015/559.

Payments in respect of relevant liabilities

6.—(1) The Secretary of State may determine whether a payment is to be made in respect of a relevant liability.

- (2) Without limit to the power in paragraph (1), a payment may be made—
- (a) to, or on behalf of, an eligible person in respect of a relevant liability of the eligible person; or
 - (b) where paragraph (3) applies.
- (3) This paragraph applies where—
- (a) an eligible person—
 - (i) has died;
 - (ii) has been dissolved or wound up (within the meaning of the Companies Act 2006⁽⁸⁾); or
 - (iii) is bankrupt or insolvent; and
 - (b) the Secretary of State is satisfied that a relevant liability of a person falling within paragraph (a) is not also a relevant liability of any other eligible person.
- (4) For the purposes of this regulation, the amount of any payment to be made is to be determined by the Secretary of State in accordance with regulation 7.
- (5) In this regulation—
- (a) “bankrupt” has the same meaning as that given in section 381(1) of the Insolvency Act 1986⁽⁹⁾ (“Bankrupt” and associated terminology); and
 - (b) “insolvent” has the same meaning as that given in section 247(1)⁽¹⁰⁾ of that Act (meaning of “insolvency” and “go into liquidation”).

Determination of amount of payment to be made in respect of a relevant liability

7.—(1) In determining the amount of any payment to be made under regulation 6 in the circumstances specified in each of paragraphs (2) to (7), the Secretary of State must have regard to the relevant matters specified in each of those paragraphs, as appropriate.

(2) Where an award of damages has been made by a court against an eligible person, the relevant matters are the amount of—

- (a) the award;
- (b) the legal and associated costs awarded to the claimant; and
- (c) any legal and associated costs incurred by or on behalf of the eligible person.

(3) Where, in any legal proceedings, a settlement has been agreed to by, or on behalf of an eligible person, the relevant matters are the amount of—

- (a) any sum paid or payable by the eligible person in relation to the claimant’s claim for damages;
- (b) the eligible person’s contribution towards any legal and associated costs incurred by the claimant; and
- (c) any legal and associated costs incurred by or on behalf of the eligible person.

⁽⁸⁾ 2006 (c. 46).

⁽⁹⁾ 1986 (c. 45). Section 381(1) of the Insolvency Act 1986 was amended by the Enterprise and Regulatory Reform Act 2013, section 71(3), Schedule 19, paragraphs 1, 52(1) and (2).

⁽¹⁰⁾ Section 247(1) of the Insolvency Act 1986 was amended by the Enterprise Act 2002, section 248(3), Schedule 17, paragraphs 9, 33(1 and (2).

(4) Where, in any legal proceedings, a Court has declined to award damages against an eligible person, the relevant matters are—

- (a) the amount of any legal and associated costs incurred by or on behalf of the eligible person; and
- (b) the extent to which those costs are not recoverable either from the claimant or from the Legal Aid Agency under regulations⁽¹¹⁾ made by virtue of section 26(5) of the Legal Aid, Sentencing and Punishment of Offenders Act 2012⁽¹²⁾ (costs in civil proceedings).

(5) Where, otherwise than in the course of legal proceedings, an eligible person has agreed to make a payment in settlement of any claim that has or may be brought against the eligible person, or otherwise, in relation to a relevant liability, the relevant matters are the amount of—

- (a) the payment agreed; and
- (b) any legal or associated costs incurred by or on behalf of the eligible person in connection with the claim.

(6) Where, otherwise than in the course of legal proceedings, an eligible person has agreed to make any contribution towards legal or associated costs incurred by a person in connection with that person's claim against the eligible person, or otherwise in respect of a relevant liability of the eligible person, the relevant matters are the amount of—

- (a) that contribution; and
- (b) any legal or associated costs incurred by or on behalf of the eligible person in connection with the claim.

(7) Where an eligible person has agreed to be bound by the determination of any person or body as to the making of a payment by the eligible person in respect of a relevant liability, the relevant matters are the amount of—

- (a) the payment;
- (b) any legal or associated costs incurred by the claimant in connection with the claim; and
- (c) any legal or associated costs incurred by or on behalf of the eligible person in connection with the claim.

Circumstances in which payments are not to be made

8. Without limit to the Secretary of State's powers under regulation 6, no payments may be made in respect of a relevant liability of an eligible person or a person falling within paragraph (3)(a) of that regulation where—

- (a) the eligible person has made an admission of liability, without first obtaining the Secretary of State's written consent;
- (b) liability has been determined by a court in proceedings conducted by, or on behalf of, the eligible person, otherwise than in consultation with the Secretary of State;
- (c) the eligible person has not complied with a condition imposed by the Secretary of State relating to a claim;
- (d) a payment falls to be made by the eligible person and, without first obtaining the Secretary of State's written consent, the eligible person agrees to—
 - (i) be bound by the determination of any person or body as to the making of a payment by the eligible person in respect of a relevant liability; or

⁽¹¹⁾ S.I. 2013/611.

⁽¹²⁾ 2012 (c. 10).

- (ii) make any other payment in respect of the relevant liability, otherwise than in the course of legal proceedings or in consequence of a settlement of legal proceedings agreed to by the eligible person;
- (e) the payment would be of an amount less than the amount which is, for the time being, specified by the Secretary of State as being the minimum amount to be paid in respect of a relevant liability of an eligible person; or
- (f) the eligible person has failed, whether fully or in part, to comply with a notice under regulation 10.

Payments on account

9.—(1) Without limit to the powers of the Secretary of State under regulation 6, where a payment falls to be made by an eligible person in connection with a relevant liability and the Secretary of State has not yet determined whether a payment is to be made in respect of the relevant liability, the Secretary of State may make a payment on account to, or on behalf of, the eligible person in respect of the relevant liability.

(2) Where the amount of any payment on account under paragraph (1) exceeds any amount subsequently determined under regulation 7 as being the amount of payment to be made in connection with a relevant liability of an eligible person, the excess is recoverable from the eligible person.

(3) Where, in accordance with the powers in regulation 6, the Secretary of State determines that no payment is to be made, the whole of the amount of any payment on account made is recoverable from the eligible person.

Information and assistance to be provided by eligible persons

10.—(1) For the purposes of the Scheme, the Secretary of State may, by notice in writing, require an eligible person to provide the Secretary of State with any assistance or information specified by the Secretary of State in the notice.

(2) A notice under paragraph (1) may specify—

- (a) the date by which the specified assistance or information must be provided; and
- (b) the manner in which the assistance or information is to be provided.

(3) An eligible person must comply with a notice under paragraph (1).

Directions and guidance

11. The Secretary of State must make the following information available to eligible persons in such form and at such times as the Secretary of State considers appropriate—

- (a) any directions given by the Secretary of State under section 71(6) of the 2006 Act; and
- (b) any guidance given by the Secretary of State to any of the bodies specified in that section.

We consent:

20th February 2019

20th February 2019

Craig Whittaker
Paul Maynard
Two of the Lords Commissioners of Her
Majesty's Treasury,
Her Majesty's Treasury
Matt Hancock
Secretary of State,
Department of Health and Social Care

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations establish the National Health Service Clinical Negligence Scheme for General Practice (the “Scheme”) and come into force on 1st April 2019. The Regulations apply only in relation to services provided as part of the NHS in England.

Regulation 2 defines terms used in the Regulations and regulation 3 establishes the Scheme, sets out its purpose and provides for the Secretary of State to administer the Scheme.

The indemnity provided under the Scheme covers the clinical negligence liabilities of GPs (and others working in a general practice setting) incurred on or after 1st April 2019 in connection with the provision of NHS services provided by general practice. The Scheme applies from 1st April 2019 in respect of all liabilities within its scope. This means that, from that date, GPs and others providing NHS services in a general practice setting will be indemnified under the Scheme in relation to such liabilities. There are no membership requirements or any other formal processes that need to be completed for the indemnity under the Scheme to apply.

The Scheme is an ‘occurrence-based’ scheme which means that, even if a person is no longer practising or working in general practice, liabilities incurred whilst they were practising continue to be covered.

The main NHS services within the scope of the Scheme are primary medical services that are provided under contractual arrangements and agreements made under Part 4 of the National Health Service Act 2006. The Scheme also provides indemnity for clinical negligence liabilities incurred in respect of other NHS services provided by general practice but only if a provider’s principal activity is to provide primary medical services. The intention is to provide a state indemnity scheme that covers all clinical negligence liabilities of any person carrying out an activity connected with the provision of NHS services as part of the delivery of such services by general practice.

The NHS services provided by general practice that are within scope of the Scheme but which are not primary medical services are referred to in the Regulations as “ancillary health services”. They include public health services provided as part of the NHS and other NHS services, for example, those commissioned directly from general practice by clinical commissioning groups or local authorities.

Where a GP practice’s principal activity is to provide primary medical services, GPs and others in the GP practice who are carrying out activities in connection with the provision of NHS services, will be covered under the Scheme in respect of clinical negligence liabilities arising from such activities. Conversely, where a large organisation is providing a package of NHS health and other services that include primary medical services, the organisation will be covered under the Scheme in relation to the primary medical services it provides but, if the organisation’s principal activity is not the provision of primary medical services, it will not be covered in respect of any other NHS services it provides.

Regulation 4 specifies the persons who are eligible persons for the purposes of the Scheme. This includes any person with whom a contractual arrangement or agreement has been made or entered into under Part 4 of the National Health Service Act 2006 Act (i.e. contracts and agreements under which primary medical services are to be provided). Where the provision of such services are sub-contracted out to another person, the sub-contractor is also an eligible person under the Scheme.

Clinically negligent acts or omissions of an eligible person’s employees or others engaged or permitted by an eligible person to carry out activities connected to the provision of primary medical

services or other NHS services for the eligible person, are also covered under the Scheme. This would include locums or trainees working in a general practice setting.

Regulation 5 specifies the liabilities covered under the Scheme. These relate primarily to clinical negligence liabilities arising from a breach of a duty of care owed to a third party by an eligible person in connection with NHS activities that are within the scope of the Scheme.

Regulations 6 to 9 deal with payments under the Scheme, including regulation 8 which specifies the circumstances in which no payments are to be made under the Scheme unless the Secretary of State decides otherwise.

Regulation 10 enables the Secretary of State to require an eligible person to provide information and assistance to the Secretary of State for the purposes of the Scheme.

Under regulation 11, the Secretary of State is under a duty to make information available to eligible persons about directions or guidance given by the Secretary of State for the purposes of the Scheme.

An impact assessment relating to this instrument has been prepared but is not publically available as it contains legally privileged, confidential and commercially sensitive information. A summary impact assessment of the impact of these Regulations is published with the Explanatory Memorandum alongside the instrument on www.legislation.gov.uk. Copies may also be obtained from the Department of Health and Social Care, 39 Victoria Street, London, SW1H 0EU.