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WELSH STATUTORY INSTRUMENTS

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**2019 No. 422 (W. 97)**

**NATIONAL HEALTH SERVICE, WALES**

**The National Health Service (Clinical Negligence Scheme) (Wales) Regulations 2019**

<i>Made</i>	- - - -	<i>4 March 2019</i>
<i>Laid before the National Assembly for Wales</i>	- -	<i>5 March 2019</i>
<i>Coming into force</i>	- -	<i>1 April 2019</i>

The Welsh Ministers make the following Regulations in exercise of the powers conferred by sections 30, 47(1) and (2), and 203(9) and (10) of the National Health Service (Wales) Act 2006<sup>(1)</sup>.

**Title, commencement and application**

1.—(1) The title of these Regulations is the National Health Service (Clinical Negligence Scheme) (Wales) Regulations 2019.

(2) These Regulations come into force on 1 April 2019.

(3) These Regulations apply in relation to Wales.

**Interpretation**

2. In these Regulations—

“the Act” (“*y Ddeddf*”) means the National Health Service (Wales) Act 2006;

“eligible body” (“*corff cymwys*”) means a body specified in regulation 4;

“Local Health Board” (“*Bwrdd Iechyd Lleol*”) means a Local Health Board established in accordance with section 11(2) of the Act;

“member” (“*aelod*”) means an eligible body which is a member of the Scheme;

“membership year” (“*blwyddyn aelodaeth*”) means, in respect of any eligible body, any 12 month period starting on 1 April during which the body is a member of the Scheme;

“NHS Trust” (“*Ymddiriedolaeth GIG*”) means a National Health Service Trust established in accordance with section 18(2) of the Act;

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(1) 2006 c. 42. Section 30 was amended by section 166 of, and paragraph 1 of Schedule 15(1) to, the Health and Social Care Act 2008 (c. 14); and by section 306(4) of, and paragraph 22 of Schedule 7 to, the Health and Social Care Act 2012 (c. 7).

“primary medical services” (“*gwasanaethau meddygol sylfaenol*”) means health services provided under a contract, arrangement or agreement made under or by virtue of the following sections of the Act—

- (a) section 41(2) (primary medical services);
- (b) section 42(1) (general medical services contracts);
- (c) section 50 (arrangements by Local Health Boards for the provision of primary medical services);

“primary medical services provider” (“*darparwr gwasanaethau meddygol sylfaenol*”) means the person who has entered into a contract to provide primary medical services in accordance with section 41(2)(b), 42 or 50 of the Act:

“relevant function” (“*swyddogaeth berthnasol*”) means—

- (a) arranging for the provision of services for the purposes of the health service<sup>(2)</sup>;
- (b) providing services for the purposes of the health service;
- (c) exercising functions in relation to the health service;
- (d) providing primary medical services;
- (e) exercising powers under, or by virtue of, section 7 of the Health and Medicines Act 1988<sup>(3)</sup>;
- (f) exercising powers under section 169 of, or paragraphs 19 and 20 of Schedule 3 to, the Act;

“relevant health services” (“*gwasanaethau iechyd perthnasol*”) means primary medical services provided in Wales for the purposes of the health service;

“the Scheme” (“*y Cynllun*”) means the Clinical Negligence Scheme for NHS Trusts and Local Health Boards established by regulation 3.

### **Clinical Negligence Scheme for NHS Trusts and Local Health Boards**

**3.—**(1) There is hereby established a scheme, to be known as the Clinical Negligence Scheme for NHS Trusts and Local Health Boards.

(2) The purpose of the Scheme is to enable an eligible body 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 Scheme is to be administered by the Welsh Ministers.

### **Eligible bodies**

**4.** The bodies which are eligible to be a member of the Scheme are—

- (a) a NHS Trust, or
- (b) a Local Health Board.

### **Membership of the Scheme**

**5.—**(1) An eligible body may apply to the Welsh Ministers to become a member of the Scheme.

(2) An application made in accordance with paragraph (1) must—

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(2) “The health service” is defined in section 206(1) of the National Health Service (Wales) Act 2006.

(3) The functions of the Secretary of State were transferred to the National Assembly for Wales by virtue of the National Assembly for Wales (Transfer of Functions) Order 1999 ([S.I. 1999/672](#)). Those functions are exercisable, in relation to Wales, by the Welsh Ministers by virtue of section 162 of, and paragraph 30 of Schedule 11 to, the Government of Wales Act 2006 ([c. 32](#)).

- (a) be made in writing,
  - (b) be made in such form and be submitted in such manner as the Welsh Ministers 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 Welsh Ministers may require.
- (3) At any time after receiving an application and before determining it, the Welsh Ministers may in writing require the applicant to provide such further information as the Welsh Ministers consider necessary for the purposes of determining the application.
- (4) Information that may be required in accordance with paragraphs (2) and (3) includes—
- (a) the nature of the applicant’s functions;
  - (b) the number of employees and contractors;
  - (c) qualifications and experience of such employees and contractors;
  - (d) details of any previous claims in which the applicant has been the defendant in respect of personal injury claims made as a result of the exercise of any relevant function;
  - (e) such other information as the Welsh Ministers may request for the purposes of determining the application.
- (5) The Welsh Ministers must—
- (a) within 6 weeks of receiving an application made in accordance with the requirements in paragraphs (2) and (3), 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.
- (6) In determining whether to grant an application, the Welsh Ministers must have regard to—
- (a) the information provided by the applicant, and
  - (b) such other factors as the Welsh Ministers consider relevant.
- (7) Where an eligible body’s application is granted, that body’s membership of the Scheme starts on the date specified in the notice given in accordance with paragraph (5)(b).
- (8) For the purposes of paragraph (4)(b) and (c), reference to “contractors” is to be construed in accordance with regulation 9(2).

### **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) A member of the Scheme may cancel its membership of the Scheme by giving notice of the cancellation in writing to the Welsh Ministers.
- (3) Where a notice under paragraph (2)—
- (a) is given before 1 September in a membership year, the notice takes effect at the end of that membership year;
  - (b) is given on or after 1 September in a membership year, the notice takes effect at the end of the following membership year.

### **Cancellation of membership by the Welsh Ministers**

- 7.—(1) The Welsh Ministers may cancel a member’s membership of the Scheme in any of the circumstances specified in paragraphs (2) to (4).

(2) The circumstances specified in this paragraph are where the member is liable to make a payment to the Welsh Ministers under regulation 11 (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 became due.

(3) The circumstances specified in this paragraph are where the member has failed to provide any information required under regulation 19 (duty of members to provide information)—

- (a) before the end of the period of 28 days which starts with the date on which the Welsh Ministers request the information, or
- (b) if the Welsh Ministers in writing allow a further period for providing such information, before the end of that further period.

(4) The circumstances specified in this paragraph are where the Welsh Ministers consider that it would be detrimental to the efficient administration of the Scheme or the interests of other members for the member to remain a member of the Scheme.

(5) The Welsh Ministers must inform the member by notice in writing that its membership of the Scheme is to cease with effect from a date specified in the notice and—

- (a) where the cancellation is in circumstances specified in paragraph (2), (3), or (4)—
  - (i) the date to be specified must not be less than 28 days after the date on which the notice is given, but
  - (ii) the Welsh Ministers may determine not to cancel the membership by giving the member a further notice in writing to that effect.

### **Liabilities of members**

8.—(1) The Scheme applies to—

- (a) any liability in tort under the law of England and Wales which a member of the Scheme owes to a third party in respect of or consequent upon personal injury or loss specified in paragraph (2), and
- (b) any contractual liability of a member of the Scheme—
  - (i) arising as a consequence of an arrangement to provide relevant health services referred to in regulation 9(2), and
  - (ii) specified as a qualifying liability of a contractor in regulation 9(4).

(2) The personal injury or loss referred to in paragraph (1) is personal injury or loss arising out of or in connection with any breach of a duty of care, which—

- (a) the member owes to any person in connection with the diagnosis of any illness or the care or treatment of any patient, and
- (b) is in consequence of any act or omission specified in paragraph (3).

(3) The act or omission referred to in paragraph (2) is an act or omission to act on the part of—

- (a) a person employed or engaged by the member in connection with any relevant function provided by the member, or
- (b) an employee or agent of a person engaged by the member in connection with the provision of any relevant function.

### **Other liabilities for which members are treated as liable**

9.—(1) In this regulation, “health services provider” means an NHS Trust, Local Health Board or a primary medical services provider.

(2) The Scheme applies to the qualifying liabilities of a health services provider which is not a member of the Scheme (“the contractor”) where its provision of relevant health services is the subject of an arrangement between it and another health services provider which is a member of the Scheme.

(3) Qualifying liabilities to which the Scheme applies under paragraph (2) are to be treated for the purposes of the Scheme and these Regulations as if they were liabilities of the health services provider who is a member of the Scheme and which entered into the arrangement.

(4) Qualifying liabilities of a contractor are any liability in tort under the law of England and Wales which—

- (a) the contractor owes to a third party in respect of or consequent upon personal injury or loss as specified in paragraph (5), and
- (b) is in consequence of the arrangement referred to in paragraph (2).

(5) The personal injury or loss referred to in paragraph (4)(a) is personal injury or loss arising out of or in connection with any breach of a duty of care which—

- (a) the contractor owes to any person in connection with the diagnosis of any illness or the care or treatment of any patient, and
- (b) is in consequence of any act or omission specified in paragraph (6).

(6) The act or omission referred to in paragraph (5)(b) is an act or omission to act in connection with the provision of relevant health services on the part of—

- (a) the contractor,
- (b) a person employed or engaged by the contractor, or
- (c) an employee or agent of a person engaged by the contractor.

### **Determination of amounts payable by members**

**10.—**(1) The Welsh Ministers must determine the amount which each member of the Scheme must pay to the Welsh Ministers in respect of each membership year.

(2) In determining the amount in paragraph (1) in respect of any member (“M”), the Welsh Ministers may have regard to—

- (a) the Welsh Ministers’ estimate of the total amount which, by virtue of regulation 13 (payments out of the Scheme), is likely to be payable during that membership year in respect of all liabilities to which the Scheme applies;
- (b) the nature of M’s relevant functions;
- (c) the number of M’s employees and contractors who are engaged in M’s performance of a relevant function or any part of a relevant function;
- (d) the qualifications and experience of those employees and contractors;
- (e) any agreement in respect of M which falls within regulation 13(3)(c) (agreement that the Scheme is to cover a future claim in respect of liability incurred before membership starts);
- (f) any agreement in respect of M which falls within regulation 13(5)(c) (agreement that the Scheme is to cover existing claim not met before membership ceases);
- (g) any agreement in respect of M which falls within regulation 14(2)(a) (agreement on payment of additional contribution that the Scheme is to cover a claim in respect of liability incurred before membership ceases);
- (h) the Welsh Ministers’ assessment of—
  - (i) the likely effectiveness of any steps being taken, or to be taken, by M as to the manner in which M exercises any relevant function for the purpose of reducing the incidence of liabilities in connection with those functions to which the Scheme applies, and

- (ii) the effectiveness of any steps which have already been taken for that purpose;
  - (i) any other factor relating to M or any other member of the Scheme which the Welsh Ministers consider relevant to the determination under paragraph (1).
- (3) In respect of each membership year, the Welsh Ministers must give each member notice in writing specifying the amount determined in respect of that member in accordance with paragraph (1).
- (4) Except as stated in paragraph (5), a notice given in accordance with paragraph (3) must be given no later than 31 December in the membership year before that to which the notice relates.
- (5) In the case of any member admitted to the Scheme—
- (a) the notice in respect of the first membership year must be given no later than 6 months after the date on which the Welsh Ministers receive the member's application in accordance with regulation 5 (membership of the Scheme), and
  - (b) the notice in respect of the second membership year must be given no later than 1 July in that membership year.
- (6) For the purposes of paragraph (2)(c) and (d), reference to "contractors" is to be construed in accordance with regulation 9(2).
- (7) For the purposes of paragraph (5), reference to the "the first membership year" of a body which is a member of the Scheme is to the whole or part of any membership year immediately following any period during which the body was not a member.

#### **Duty of members to make contributions to the Scheme**

- 11.**—(1) Each member of the Scheme must, in respect of each membership year, pay to the Welsh Ministers the amount determined in respect of the member under regulation 10(1) (determination of amounts payable by members).
- (2) Except as stated in paragraph (3), a member which receives a notice under regulation 10(3) of the amount payable in respect of a membership year must pay the amount due—
- (a) in accordance with such arrangement as may be agreed by the Welsh Ministers and the member (which may include payment in instalments to be made at agreed times);
  - (b) if no agreement is reached by 1 March immediately before the start of the membership year, by such time and in such manner as the Welsh Ministers may decide.
- (3) Where a member admitted to the Scheme receives a notice under regulation 10(3) in respect of a membership year, the member must pay—
- (a) the amount due in respect of the first membership year no later than 8 months after the date on which the Welsh Ministers receive the member's application under regulation 5 (membership of the Scheme), and
  - (b) the amount due in respect of the second membership year no later than 1 August in that membership year.
- (4) For the purposes of paragraph (3), reference to "the first membership year" of a body which is a member of the Scheme is to be construed in accordance with regulation 10(7).

#### **Revision of determination of payable amount**

- 12.**—(1) Paragraph (2) applies where the Welsh Ministers identify before the end of a membership year that the amount determined by them in accordance with regulation 10(1) as being payable by the member in respect of that year—
- (a) is incorrectly calculated,

- (b) is determined by reference to information which was incorrect, or
- (c) should be reconsidered in light of further information that has become available to the Welsh Ministers.
- (2) The Welsh Ministers—
  - (a) must reconsider the amount determined, and
  - (b) at any time before the end of the membership year in question, may revise the amount payable by the member in respect of that year.
- (3) The Welsh Ministers must give the member notice in writing of any revised amount determined in accordance with paragraph (2)(b) and the member must pay any amount that remains due in respect of the membership year—
  - (a) in accordance with such arrangements as may be agreed between the Welsh Ministers and the member (which may include payment in instalments to be made at agreed times), and
  - (b) if no agreement is reached by the end of the membership year, by such time and in such manner as the Welsh Ministers may decide.
- (4) The reference in paragraph (1) to an amount determined by the Welsh Ministers in accordance with regulation 10(1) includes any revised amount determined in accordance with paragraph (2)(b).

#### **Payments out of the Scheme: liabilities of members**

**13.**—(1) Where a payment falls to be made by a member of the Scheme in connection with a claim in respect of a liability to which the Scheme applies, the Welsh Ministers may pay to the member, or on the member's behalf, an amount determined in accordance with regulation 17.

- (2) No payment may be made under paragraph (1)—
  - (a) in respect of any liability of the member which is excluded from the Scheme by any of paragraphs (3) to (5), or
  - (b) in respect of any liability of, or payment by, the member which is excluded from the Scheme by regulation 15 (exclusions).
- (3) Any liability which was incurred by an eligible body before it became a member of the Scheme is excluded from the Scheme unless—
  - (a) the claim against the eligible body in respect of the liability was made after the start of its membership of the Scheme,
  - (b) the Welsh Ministers are satisfied that the eligible body informed the Welsh Ministers before the end of the qualifying period that the claim had been made,
  - (c) the Welsh Ministers agreed before the start of the eligible body's membership that any liability of the body that results from a claim to which sub-paragraphs (a) and (b) apply should not be excluded from the Scheme, and
  - (d) that agreement remained in force on the date on which the claim against the eligible body falls to be met.
- (4) Any liability of a member which falls to be met after the member gives notice of cancellation under regulation 6(2) (cancellation of membership by a member) but before membership has ceased is excluded from the Scheme unless the Welsh Ministers are satisfied that the liability would have fallen to be met at that time irrespective of the member's decision to give such a notice.
- (5) Any liability of an eligible body which falls to be met after its membership of the Scheme has ceased is excluded from the Scheme unless—
  - (a) the claim against the eligible body in respect of the liability was made before the body's membership ceased,

- (b) the Welsh Ministers are satisfied that the eligible body informed the Welsh Ministers before the end of the qualifying period that the claim had been made,
- (c) the Welsh Ministers agreed before the eligible body's membership ceased that any liability of the body that results from a claim to which sub-paragraphs (a) and (b) apply should not be excluded from the Scheme, and
- (d) that agreement remained in force on the date on which the eligible body's membership ceased.

(6) In paragraphs (3)(b) and (5)(b), the “qualifying period” is the period of 14 days starting with the date on which the member became aware that a claim had been made or, if earlier, the date on which the Welsh Ministers consider that the member ought to have become aware that a claim had been made.

### **Payments out of the Scheme: liabilities of former members**

#### **14.—(1) Where—**

- (a) a payment falls to be made by an eligible body (“B”) which has at any time been a member of the Scheme in connection with a claim in respect of a liability to which the Scheme applies, and
  - (b) the claim relates to a breach of the duty of care by B whilst it was a member of the Scheme,
- the Welsh Ministers may, if the conditions specified in paragraph (2) are met, pay to B or on B's behalf an amount determined by the Welsh Ministers in accordance with regulation 17.

#### **(2) The conditions are that—**

- (a) before B's membership of the Scheme ceases, the Welsh Ministers agree with B that, in respect of the membership year immediately preceding the cessation of B's membership, the amount to be paid by B under regulation 11 (duty of members to make contributions to the Scheme) is also to include an additional amount determined for the purposes of this regulation,
  - (b) that amount is determined by the Welsh Ministers as being sufficient to meet any liabilities of B falling within paragraph (1) which were incurred whilst B was a member but fall to be met after the date on which B's membership ceases, and
  - (c) before that date, B either pays the additional amount in full or enters into an agreement with the Welsh Ministers to pay it in instalments.
- (3) No payment may be made under paragraph (1) in respect of any liability of, or payment by, B which is excluded from the Scheme by regulation 15 (exclusions).

### **Exclusions**

**15.—(1)** Except to such extent as the Welsh Ministers may determine, the following are excluded from the Scheme—

- (a) any liability admitted by a member without first obtaining the Welsh Ministers' consent in writing;
- (b) any liability determined by a Court in proceedings which are conducted by a member otherwise than in consultation with the Welsh Ministers;
- (c) any payment falling to be made by a member where the member has not complied with any condition imposed by the Welsh Ministers relating to a claim;
- (d) any payment falling to be made by a member where, without first obtaining the Welsh Ministers' consent in writing, the member agrees—



- (i) to be bound by the determination of any person or body as to the making of a payment by that member in respect of a liability, or
    - (ii) to make any other payment in respect of the liability otherwise than in the course of legal proceedings or in consequence of a settlement of legal proceedings agreed to by the member;
  - (e) any liability that is of an amount less than the amount which is for the time being agreed between a member and the Welsh Ministers as being the minimum amount of any liability in respect of which a payment is to be made under the Scheme;
  - (f) any liability of a primary medical services provider which was either incurred, or falls to be met, in a membership year in relation to which that primary medical services provider was included in a notification to the Welsh Ministers by the Local Health Board.
- (2) In paragraph (1)—
- (a) references to “member” include a former member of the Scheme—
    - (i) in respect of which the requirements of regulation 13(5)(c) and (d) are met (agreement that the Scheme is to cover existing claim not met before membership ceases), or
    - (ii) to which regulation 14 applies (liabilities of former members);
  - (b) in sub-paragraph (f), “notification” means a list of primary medical services providers whose qualifying liabilities are not to be covered by the Scheme for the membership year.

#### **Payments out of the Scheme: liabilities for which members are treated as liable**

**16.**—(1) Paragraph (2) applies to any payment in connection with a claim in respect of a qualifying liability falling within regulation 9 (other liabilities for which members are treated as liable) where the payment falls to be made by a member of the Scheme which under regulation 9(3) is treated as being liable in respect of the claim.

(2) Regulations 13 to 15 (circumstances in which payments are to be made out of the Scheme in respect of liabilities of members and former members) are to apply to enable payments to be made to or on behalf of any member of the Scheme in respect of qualifying liabilities as those regulations apply in respect of the member’s own liabilities.

(3) In the application of regulation 13, 14 or 15 for the purposes of paragraph (2), references to anything being done by, to or against a member in respect of a liability to which the Scheme applies includes references to it being done in respect of a qualifying liability for which the member is treated as being liable.

#### **Determining the amount of any payment to be made out of the Scheme**

**17.**—(1) In respect of each liability to which the Scheme applies, the Welsh Ministers must determine the amount of any payment which is to be made under regulation 13 or 14 (payments out of the Scheme in respect of liabilities of members and former members).

(2) In determining the amount of the payment to be made in circumstances specified in each of paragraphs (3) to (8), the Welsh Ministers must have regard to the relevant matters specified in that paragraph.

(3) Where an award of damages has been made by a Court against a member, 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 member.

(4) Where legal proceedings are the subject of a settlement agreed to by the member, the relevant matters are the amount of—

- (a) any sum paid or payable by the member in relation to the claimant's claim for damages,
- (b) the member'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 member.

(5) Where, in any legal proceedings, a Court has declined to award damages against the member, the relevant matters are—

- (a) the amount of any legal and associated costs incurred by or on behalf of the member, and
- (b) the extent to which those costs are not recoverable either from the claimant or from the Legal Aid Agency under regulations made by virtue of section 26(5) of the Legal Aid, Sentencing and Punishment of Offenders Act 2012<sup>(4)</sup> (costs in civil proceedings).

(6) Where a member has, otherwise than in the course of legal proceedings, agreed to make a payment in settlement of a claim, 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 member in connection with the claim.

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

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

(8) Where a member has agreed to be bound by the determination of any person or body as to the making of a payment by that member in respect of a liability to which the Scheme applies, 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 member in connection with the claim.

(9) In this regulation, references to "member" are to be construed in accordance with regulation 15(2).

### **Power to make payments on account**

**18.**—(1) Where, in any membership year, a payment falls to be made by a member in connection with a claim in respect of which an amount may become payable by the Welsh Ministers under regulation 17 (determining the amount of any payment to be made out of the Scheme), the Welsh Ministers may make a payment on account of any amount which may become payable.

(2) A payment on account may be made to or on behalf of the member.

(3) Where the amount of any payment on account exceeds the amount subsequently determined under regulation 17 as being the amount of payment to be made in connection with the claim, the excess is recoverable from the member.

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(4) 2012 c. 10.

### **Duty of members to provide information**

**19.**—(1) In this regulation, “specified” means specified by the Welsh Ministers in a notice under paragraph (2).

(2) The Welsh Ministers may by notice in writing require a member to provide the Welsh Ministers with specified information.

(3) Specified information includes—

- (a) the nature of any relevant function carried on, or to be carried on, by the member in a specified membership year,
- (b) the number of the member’s employees and contractors who are engaged in the member’s performance of a specified relevant function or in a specified part of any such function,
- (c) the qualifications and experience of those employees and contractors, and
- (d) any event of which the member is aware which it considers might give rise to a liability to which the Scheme applies.

(4) The member must comply with a notice under paragraph (2) and must—

- (a) provide the information within 28 days of receiving the notice or within such further period as the Welsh Ministers may in writing allow,
- (b) provide the information in any specified form, and
- (c) submit the information in any specified manner.

(5) For the purposes of paragraph (3)(b) and (c), reference to “contractors” is to be construed in accordance with regulation 9(2).

### **Directions and guidance**

**20.**—(1) The Welsh Ministers must make the following information available to eligible bodies in such form and at such times as the Welsh Ministers consider appropriate<sup>(5)</sup>—

- (a) any directions which the Welsh Ministers give to a relevant body with respect to the exercise by that body of its functions in connection with administering the Scheme, and
- (b) any guidance which the Welsh Ministers give to a relevant body as to the manner in which the Scheme is to be administered.

(2) “Relevant body” means a body directed by the Welsh Ministers under section 30(5) of the Act to carry out functions in connection with the administration of the Scheme.

### **Amendment of the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004**

**21.**—(1) The National Health Service (General Medical Services Contracts) (Wales) Regulations 2004<sup>(6)</sup> are amended as follows.

(2) In Schedule 6, in paragraph 120—

(a) after sub-paragraph (2) insert—

“(2A) The Local Health Board, to the extent it considers reasonable and to the extent it may be reimbursed in accordance with the Clinical Negligence Scheme for NHS Trusts

(5) The directions and guidance given by the Welsh Ministers are available on <http://www.nwssp.wales.nhs.uk> or by making a request in writing to the Directorate for Health Policy, Primary Care Team, Welsh Government, Cathays Park, Cardiff, CF10 3NQ.

(6) [S.I. 2004/478 \(W. 48\)](#). Paragraph 120 of Schedule 6 was amended by regulation 11(33) of the National Health Service (Primary Medical Services) (Miscellaneous Amendments) (Wales) Regulations 2006 ([S.I. 2006/358 \(W. 46\)](#)) and paragraph 5(a) to (e) of Schedule 2 to the Health Care and Associated Professions (Indemnity Arrangements) Order 2014 ([S.I. 2014/1887](#)). There are other amendments but none are relevant.

and Local Health Boards established by regulation 3 of the 2019 Regulations, shall indemnify the contractor in respect of that contractor's qualifying liabilities as specified in regulation 9(4) of the 2019 Regulations, provided the contractor—

- (a) complies with the Local Health Board's claims management protocol for contractors (as amended from time to time); and
  - (b) does not have any other indemnity arrangement in force in connection with clinical services which the contractor provides under the contract at the time the qualifying liability arose.”;
- (b) in sub-paragraph (3)—
- (i) at the end of paragraph (aa) omit “and”;
  - (ii) for paragraph (b) substitute—
    - “(b) a contractor shall be regarded as having in force in relation to it an indemnity arrangement—
    - (i) if there is an indemnity arrangement in force in relation to a person employed or engaged by it in connection with clinical services which that person provides under the contract or, as the case may be, sub-contract; or
    - (ii) for its qualifying liabilities specified in regulation 9(4) of the 2019 Regulations, to the extent provided for under paragraph 120(2A);”;
  - (iii) after paragraph (b) insert—
    - “(c) “the 2019 Regulations” means the National Health Service (Clinical Negligence Scheme) (Wales) Regulations 2019.”

## Revocation

**22.** The National Health Service (Clinical Negligence Scheme) Regulations 1996(7) are revoked.

4 March 2019

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Minister for Health and Social Services, one of  
the Welsh Ministers

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## EXPLANATORY NOTE

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

These Regulations, which apply in relation to Wales, make provision in connection with the Clinical Negligence Scheme for NHS Trusts and Local Health Boards in Wales (“the Scheme”). The Scheme enables members exercising functions in connection with the National Health Service in Wales to make provision for meeting liabilities to which the Scheme applies. These Regulations revoke and replace the National Health Service (Clinical Negligence Scheme) Regulations 1996 (S.I. 1996/251).

Regulation 3 sets out the Scheme’s purpose and provides that it will be administered by the Welsh Ministers. Regulation 4 lists the bodies eligible to become members and regulation 5 sets out the procedure for eligible bodies to become a member. Membership may be cancelled under regulation 6 by any member of at least 3 years standing. The Welsh Ministers may also cancel a body’s membership in accordance with regulation 7 on grounds which include non-payment of a member’s contribution to the Scheme.

Regulations 8 and 9 set out the liabilities to which the Scheme applies. Regulation 8 provides that the Scheme applies to contractual liabilities and liabilities in tort which a member owes to a third party in connection with personal injury or loss arising from negligent acts or omissions in the exercise of specified health service functions of the member. In the circumstances set out in regulation 9, the Scheme also applies to liabilities in negligence which a non-member owes to third parties and for which members of the Scheme are treated as liable. Regulation 9 provides that the member of the Scheme is to be treated as liable in respect of negligence liabilities that arose whilst relevant health services were being provided by non-members under an arrangement with a member of a Scheme.

Regulations 10 to 12 contain provision for the calculation (and in certain circumstances the revision) of amounts which members are required to contribute for the purposes of the Scheme and sets out when such contributions must be made.

Regulations 13 to 18 set out the circumstances in which payments are to be made by the Welsh Ministers under the Scheme to or on behalf of members. Regulation 13 deals with payments in respect of the liabilities of members, regulation 14 deals with payments in respect of the liabilities of former members in respect of events occurring during membership and regulation 15 specifies circumstances in which any such liabilities are excluded. Regulation 16 applies regulations 13 to 15 with modifications to the cases where specified members of the Scheme are treated as liable in respect of the negligence liabilities of others (as set out in regulation 9). Amounts to be paid are determined in accordance with regulation 17 and provision for the making of payments on account is contained in regulation 18.

Regulation 19 sets out the requirements for members to provide information to the Welsh Ministers for the purposes of the Scheme. Regulation 20 requires the Welsh Ministers to make available to eligible bodies any directions or guidance which the Welsh Ministers give to any body directed to administer the Scheme on behalf of the Welsh Ministers. Regulation 21 makes consequential amendments to the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004 (S.I. 2004/478 (W. 48)). Regulation 22 revokes the National Health Service (Clinical Negligence Scheme) Regulations 1996.

The Welsh Ministers’ Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, it was not considered necessary to carry

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out a Regulatory Impact Assessment for this instrument as no impact on the private or voluntary sectors is foreseen.