

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

This Explanatory Memorandum has been prepared by Health and Social Services Department and is laid before the National Assembly for Wales in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1

Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of The National Health Service (Clinical Negligence Scheme) (Wales) Regulations 2019

Vaughan Gething
Minister for Health and Social Services
5 March 2019

PART 1

1. Description

These Regulations 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.

2. Matters of special interest to the Constitutional and Legislative Affairs Committee

None

3. Legislative background

The powers of the Welsh Ministers that are being relied upon to introduce the regulations are sections 30, 47(1), (2) and (4), and 203(9) and (10) of the National Health Service (Wales) Act 2006.

These Regulations revoke the National Health Service (Clinical Negligence Scheme) Regulations 1996 (S.I. 1996/251). These Regulations also make consequential amendments to the National Health Service (General Medical Services Contract) (Wales) Regulations 2004 (S.I. 2004/478 (W.48)).

These Regulations are being made under the negative resolution procedure

4. Purpose and intended effect of the legislation

Clinical negligence cover is a condition of registration in the UK for all regulated healthcare professionals, and in the case of medical practitioners, a condition of licence under s.44C of the Medical Act 1983. The cover can be an insurance policy, an indemnity arrangement, or a combination of both. .

There has been concern about increasing indemnity costs, which could potentially drive GPs away from the profession, resulting in an impact on services. It is estimated that indemnity premiums have increased by 7% per year on average between 2013 and 2017. Among the factors driving the increasing cost of indemnity is an ageing population; technological innovations in medicine which keep people alive longer; an increase in people living with complex conditions and an increasing claims culture. There is no evidence to suggest that deterioration in the quality of care has acted as a driver to increase the cost of indemnity. Increases in the last two years are estimated to be over 10% in total. The rising cost of indemnity subscriptions has been cited as one of the reasons why GPs are reducing their hours, and if the trend continues, may create a further shortage of GPs.

On the 14th May 2018, the Minister for Health and Social Services announced that the Welsh Government would introduce a state backed scheme to provide clinical negligence indemnity for providers of GP services in Wales. The scheme, which is planned to come into force on 1 April 2019, will cover all contracted GPs and other health professionals working in NHS general practice.

The scheme will help to address the concerns of GPs about the affordability of professional indemnity premiums and will deliver a sustainable, long term solution to address the increasing costs of professional indemnity.

The scheme will be aligned as far as possible to the state backed scheme to be introduced for providers of GP services in England on 1 April 2019. This will ensure that GPs in Wales are not at a disadvantage relative to GPs in England, will also help to ensure that GP recruitment and cross border activity will not be adversely affected by different schemes operating in England and Wales

The Regulations establish the Clinical Negligence Scheme for NHS Trusts and Local Health Boards to provide for all qualifying liabilities, from 1 April 2019, in tort and in contract.

The indemnity provided under the Scheme covers the clinical negligence liabilities of members (Local Health Boards and NHS Trusts) as well as those of non-member contractors who provide primary medical services by virtue of an arrangement with a member of the Scheme (e.g. a general medical services contract). The Scheme applies from 1 April 2019 in respect of all liabilities within its scope. This means that, from that date, members and contractors will automatically be covered by the Scheme in relation to such liabilities.

The Scheme will provide discretionary cover in respect of liabilities in tort (under the law of England and Wales) that arise in consequence of a breach of duty of care by a member or contractor (or other person employed, engaged or employed by a person engaged by a member or contractor) which results in physical injury or loss to a person. Claims made under the Scheme are expected to consist of mainly clinical negligence claims.

The Scheme will not cover private work, complaints, involvement in coroners' cases, GMC hearings and other matters relating to professional regulation. Any provision of these services will necessitate taking out separate indemnity insurance to cover private work and the other aspects not covered by the Scheme.

In November 2018, The Minister for Health and Social Services confirmed that Shared Services Partnership – Legal and Risk Services will operate that state backed scheme for GPs in Wales (Future Liability Scheme)

This Statutory Instrument is essential to establish the Scheme and facilitate its operation.

5. Consultation

Throughout the development of the policy for the Scheme, the Welsh Government has engaged, on an ongoing basis, with key stakeholders affected by the proposed changes, arising from the implementation of a state scheme, including Medical Defence Organisations, GPs, NHS Wales Shared Services Partnership - Legal and Risk Services and NHS Wales. This engagement process included meetings and other communications with stakeholders to assist them in understanding the proposals made and to elicit their views before final decisions were made on the Scheme policy. The process has also included the establishment of a Stakeholder Reference Group.

An informal, targeted, consultation was undertaken with the draft statutory instrument shared with stakeholders between 19th and 28th February 2019. The list of stakeholders included:

- Directors of Primary Care of Local Health Boards
- Associate Medical Directors of Local Health Boards
- Medical Directors of Local Health Boards
- Finance Directors of Local Health Boards
- Directors of Nursing of Local Health Boards
- General Practitioners Committee Wales
- Royal College of General Practitioners
- GP Practice Managers
- NHS Wales Shared Services Partnership - Legal and Risk Service

Six responses were received following the informal consultation. The responses sought clarification on the following points:

- (a) Whether the scheme is a “discretionary” scheme (in line with the current medical defence organisations and GP current indemnity arrangements) or whether the scheme is contractual (similar to commercial insurers) and the way in which discretion will be applied by the scheme operator (Shared Services Partnership - Legal and Risk Services)
 - (b) The scope of the Scheme in terms of liability in tort and contractual liability.
 - (c) The scope of the scheme in terms of who is covered and what activities are covered.
 - (d) The way in which the scheme will be funded.
 - (e) Clarity on the information which Local Health Boards may request from GPs.
 - (f) Clarity as to whether the draft Regulations would capture all of WRP activity.
- The Welsh Government responded to all queries, setting out the appropriate information and advising that the clarity sought will also be addressed in the Future Liability Scheme Guidance which will accompany Ministerial Directions in relation to the administration of the Scheme.

6. Regulatory Impact Assessment (RIA)

A Regulatory Impact Assessment has not been prepared for this instrument as it imposes no costs or no savings, or negligible costs or savings on the public, private or charities and voluntary sectors.

A wide range of options were initially considered to address the issues with GP indemnity. The criteria included compatibility with primary care policy; sustainability; legal and financial risks; and transitional arrangements from the current position. The costs and benefits of each option are not presented here in detail due to the limited information that can be included because of the confidential commercial basis on which the analysis is based.

As highlighted above, the benefits of the state backed scheme help to address the concerns of GPs about the affordability of professional indemnity premiums and will deliver a sustainable, long term solution to address the increasing costs of professional indemnity. GPs will contribute towards the cost of the scheme, through the General Medical Services Contract.

This legislation has no impact on the statutory duties (sections 77-79 of the Government of Wales Act 2006) or statutory partners (sections 72-75 of that Act).