

Explanatory Memorandum to the National Health Service (Existing Liabilities Scheme for General Practice) (Wales) Regulations 2020.

This Explanatory Memorandum has been prepared by the Directorate of Primary Care and Health Science of the Welsh Government 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 (Existing Liabilities Scheme for General Practice) (Wales) Regulations 2020. I am satisfied that the benefits justify the likely costs.

Vaughan Gething
Minister for Health and Social Services
13 March 2020

PART 1

1. Description

1.1 The National Health Service (Existing Liabilities Scheme for General Practice) (Wales) Regulations 2020 (“the Regulations”) establish the Existing Liabilities Scheme for General Practice (“the Scheme”), a direct indemnity scheme under which the Welsh Ministers will consider indemnifying clinical negligence claims made against a GP and others working in a general practice setting as a result of an act or omission prior to 1 April 2019 giving rise to a tortious liability in connection with the provision of primary medical services and other NHS services by general practice. The ‘existing liabilities’ covered by the Scheme, in the main, will be clinical negligence liabilities.

1.2 The Regulations contain provisions detailing what constitutes an “existing liability”, specify the category of existing liabilities that are within scope of the Scheme, define eligible persons, set out how payments may be made out of the scheme, specify the circumstances under which a payment may not be made, as well as creating a duty upon the Welsh Ministers to make information available about directions or guidance given by the Welsh Ministers for the purposes of the Scheme.

2. Matters of special interest to the Legislation, Justice and Constitution Committee

2.1 Section 30 (Schemes for meeting the losses and liabilities etc. of certain NHS bodies) of the National Health Service (Wales) Act 2006 has been amended by the National Health Service (Indemnities) (Wales) Act 2020, which received Royal Assent on 26 February 2020.

2.2 A Statement of Policy Intent setting out the subordinate legislation (i.e. the Regulations) to be made under the NHS (Indemnities) (Wales) Bill, as it was then, was laid at the same time as the Bill was introduced into the Assembly. The Counsel General consented the Act coming into force the day following that it gained Royal Assent. The NHS (Indemnities) (Wales) Act 2020 was Sealed under Royal Assent on 26 February 2020. Therefore the Act came into force on 27 February 2020. This has enabled the Regulations to be laid to come into force as needed. The Regulations will be laid to come into force on 6 April 2020, being laid on the day following the day on which the Bill received Royal Assent, to enable them to come into force on 6 April 2020.

3. Legislative background

3.1 The powers of the Welsh Ministers that are being relied upon to introduce the regulations are sections 30(2), (8) and (9), and 203(9) and (10) of the National Health Service (Wales) Act 2006.

3.2 Section 30 of the National Health Service (Wales) Act 2006 was amended by the National Health Service (Indemnities) (Wales) Act 2020. The number of

bodies and persons who may be indemnified within subsection 30(2) has been expanded and new subsections (8) and (9) have been incorporated into section 30 of the 2006 Act, conferring the power on the Welsh Ministers to establish direct indemnity schemes, by regulations, and setting out what such regulations may contain.

3.4 The Regulations are being made under the negative resolution procedure.

4. Purpose and intended effect of the legislation

4.1 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 section 44C of the Medical Act 1983. The cover can be an insurance policy, an indemnity arrangement, or a combination of both.

4.2 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 increased by 7% per year on average between 2013 and 2017. Among the factors driving the increasing cost 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.

4.3 On 27 February 2017, the Lord Chancellor announced¹ a change to the Personal Injury Discount Rate ("PIDR") (the rate used to calculate the damages that are payable in respect of future pecuniary losses) from 2.5% to minus 0.75%². As a result of this change, the cost of large personal injury claims increased significantly. This led to large unanticipated increases in the cost of meeting historic liabilities for Medical Defence Organisations (MDOs), the current providers of professional indemnity cover for medical practitioners. As MDOs are mutual bodies, this increase could only be covered by increasing GP indemnity premium costs further. It was estimated that indemnity premiums would need to increase by 25% to fund the change in PIDR.

4.4 In October 2017 the Secretary of State for Health and Social Care in England announced an intention to establish a government funded state backed scheme to provide clinical negligence indemnity cover for providers of GP services in England that would take effect from 1 April 2019 - a Future Liabilities Scheme (FLS). Transfer of the responsibility to consider historic liabilities (i.e. those

¹ <https://gov.wales/written-statement-gp-professional-indemnity>

² The PIDR was further changed to minus 0.25% on 15 July 2019. The effect on the indemnity market at the time of compiling this Explanatory Memorandum has not been quantified.

claims where the act or omission giving rise to the liability took place prior to 1 April 2019) from MDOs, known as the Existing Liabilities Scheme (ELS), would be subject to due diligence and successful negotiations between the UK government and the three main MDOs.

4.5 On 14th May 2018, the Cabinet Secretary for Health and Social Services announced that the Welsh Government would introduce a state backed scheme to provide clinical negligence indemnity cover for providers of GP services in Wales from 1 April 2019. The FLS was established by the National Health Service (Clinical Negligence Scheme) (Wales) Regulations 2019 and came into force on 1 April 2019. The FLS is known in Wales as the Scheme for General Medical Practice Indemnity.

4.6 In November 2018 the Minister announced that the Welsh Government was committed to covering liabilities for historic clinical negligence claims which had either been reported, or which had been incurred but not reported, prior to 1 April 2019, against GPs who were members of a MDO, subject to the completion of due diligence and satisfactory negotiations between the Welsh Ministers and the three main MDOs (i.e. an ELS for Wales).

4.7 These Regulations will establish the ELS in Wales. These Regulations will only apply to an MDO and their GP members if an existing liability is within scope of a contractual arrangement made between the Welsh Ministers and an MDO.

4.8 By establishing the ELS, together with the FLS which was introduced on 1 April 2019, the Welsh Government is future proofing for the effects, market shocks and stresses of future events relating to clinical negligence cover for providers of NHS primary medical services in Wales as part of general practice. The ELS and FLS will underpin the long term sustainability of the provision of general medical services. This will help GP recruitment and retention in Wales since no Wales based GP will be placed at a disadvantage in terms of clinical medical negligence indemnity cover, when compared with GPs based in England where the FLS and ELS schemes have also been introduced.

4.9 These Regulations establish a direct indemnity scheme for the purposes of the ELS.

4.10 The indemnity provided under these Regulations covers the clinical negligence liabilities of GPs (and others working in a general practice setting) reported, or incurred but not reported, prior to 1 April 2019 in connection with the provision of NHS services provided by general medical practice. Indemnity cover must have been in existence with an MDO that has entered into an ELS contractual agreement with the Welsh Ministers at the time the act or omission giving rise to the liability took place.

4.11 The Regulations will apply from 6 April 2020. This means that, from that date, GPs and others who provided NHS services in a general practice setting and who held indemnity cover with a MDO (that has reached ELS contractual agreement with the Welsh Ministers) may be covered by the ELS in relation to relevant liabilities, subject to a legal transfer of responsibility from the MDO.

4.12 The ELS is an ‘occurrence-based’ scheme. This means that, even if a person is no longer practising or working in general practice, liabilities incurred whilst they were practising and they were a member of an MDO on the date that the act or omission giving rise to a liability occurred, will be covered.

4.13 The Regulations contain provisions detailing what constitutes an “existing liability”; specify the category of existing liabilities that are within scope of the Scheme; define eligible persons; and set out how payments may be made out of the Scheme.

4.14 The main NHS services within the scope of the ELS Scheme are primary medical services that would have been provided under contractual arrangements and agreements made under Part 4 (Primary Medical Services) of the National Health Service (Wales) Act 2006 or predecessor legislation.

4.15 The Regulations set out the persons, and includes bodies, whose existing liabilities may be covered by the Scheme (termed “eligible persons” in the Regulations). Such persons or bodies must, on the date on which the act or omission giving rise to the existing liability occurred (termed “the relevant date” in the Regulations), have been members of an MDO with whom contractual arrangements (as described above) have been agreed with the Welsh Ministers. In addition, the person or body must, on the relevant date, have either been a Part 4 contractor, a primary medical services sub-contractor or a person providing NHS services, other than primary medical services. The latter category of persons only fall within the definition of “eligible person” if, on the relevant date, they were providing the ancillary health services under a contractual arrangement with a Part 4 contractor or primary medical services sub-contractor whose principal activity, on the relevant date, was to provide primary medical services. Existing liabilities of persons engaged or permitted to carry out a relevant function by an eligible person are also covered under the Scheme.

4.16 The Regulations set out how any payments would be made out of the Scheme, including specifying the circumstances in which payment may not be made under the ELS. Provisions are included to enable the Welsh Ministers to require the provision of information and assistance for the purposes of the ELS, as well as creating a duty upon the Welsh Ministers to make information available about directions or guidance given by the Welsh Ministers for the purposes of the ELS. The Scheme will be operated and administered on behalf of the Welsh Ministers by NHS Wales Shared Services Partnership – Legal and Risk Services (NHSWSSP – LARS).

Timing of Regulations

4.16 Section 2(2) of the NHS (Indemnities) (Wales) Act 2020 provides that the Act comes into force on the day after the day on which it receives Royal Assent.

4.17 These Regulations have been laid before the National Assembly for Wales on 13 March 2020. The Regulations will come into force on 6 April 2020. This will ensure the Welsh Ministers safeguard the continuity of professional

indemnity cover for historic liabilities of GPs at the earliest possible opportunity, whilst ensuring that the delivery of regulations underpinning ELS arrangements with MDOs takes place commensurately with the Department for Health and Social Care of the UK government.

5. Consultation

5.1 The Welsh Government engaged with key stakeholders throughout the development and implementation of the state backed GP Indemnity Scheme for Wales. These have included the MDOs, GPC Wales, NHS Wales Shared Services Partnership - Legal and Risk Services, RCGP Wales and NHS Wales. The Regulations are of a limited and discrete nature focused on the establishment of the ELS.

5.2 An informal, targeted, consultation was undertaken with the draft statutory instrument shared with stakeholders between 21 January 2020 and 10 February 2020 regarding the draft Regulations and the draft Explanatory Memorandum and Regulatory Impact Assessment. The list of stakeholders included:

- The Medical Defence Union
- The Medical and Dental Defence Union of Scotland
- The Medical Protection Society
- 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 Wales
- GP Practice Managers
- NHS Wales Shared Services Partnership - Legal and Risk Service

5.3 Six responses were received and Welsh Government has acted upon the points made and replied in each case to answer the queries raised. The responses have helped to inform a bank of Frequently Asked Questions regarding the ELS which may be found on Scheme for General Medical Practice website. The responses will not be published given the nature of the consultation.

5.4 There has not been a wider public consultation given:

- the technical and focused nature of these Regulations, and
- GPs continue to require clinical negligence cover to fulfil the requirements of section 44C of the Medical Act 1983 - the Regulations enable the provider of the indemnity to move from MDO/insurer to the Welsh Ministers.

PART 2 – REGULATORY IMPACT ASSESSMENT

6. Options

6.1 The Regulations establish the ELS for Wales, as is set out within the Explanatory Memorandum and Regulatory Impact Assessment of the NHS (Indemnities) (Wales) Act 2020.

6.2 The Regulations set out the provisions underpinning the ELS for those MDOs (and their GP members and others working in a general practice setting) who, as a result of concluding a contractual agreement with the Welsh Ministers, are relinquishing, to the Welsh Government, their responsibilities regarding general practice NHS work related indemnity.

6.3 The financial implications associated with the Regulations are assessed against a business as usual scenario.

7. Costs and benefits

7.1 The Regulations of themselves do not impose any costs on any sector or business. However, they establish the ELS for Wales which will lead to potential costs for the Welsh Government relating to the assumption by Welsh Government from participating MDOs of responsibility for considering the provision of indemnity cover in respect of NHS general practice work.

7.2 Welsh Government has commissioned external financial advisors to undertake financial due diligence in relation to the three main MDOs, covering actuarial advice in relation to potential clinical negligence liabilities incurred before 1 April 2019. The external financial advisors have provided an independent actuarial estimate of the total liabilities, including known liabilities and IBNR (incurred but not yet reported) liabilities. The actual value of the liabilities may fluctuate according to claims incidence patterns, claims notifications and the value of settled claims. The external financial advisors, in estimating IBNR, have assessed data provided by the MDOs.

7.3 Agreement by the Welsh Government to assume responsibility for the consideration of providing indemnity cover in respect of the above liabilities will only be given if an appropriate transfer of assets can be agreed with MDOs. However, the anticipated net financial exposure of Welsh Government in relation to each MDO with whom agreement is reached cannot be disclosed since this would breach the non-disclosure agreements between the MDOs and Welsh Government.

7.4 In the event of agreement being reached with all three main MDOs, the current estimate of liabilities that would be assumed by Welsh Government (subject to legal and financial due diligence and successful discussion of terms with those three MDOs) is currently anticipated to be in the region of £100m, before any transfer of assets. This estimate of liabilities is not the expected cost

to Welsh Government because it does not take account of any asset transfers from MDOs.

7.5 A commitment has been made by the Minister for Health and Social Services to provide an annual report to the National Assembly for Wales which will include the financial impact of the ELS arrangements, subject to adhering to confidentiality agreements. Please see paragraphs 9.1 and 9.2 under the heading Post Implementation Review.

Benefits

7.6 The anticipated net financial exposure to Welsh Government will represent value for money given that the ELS arrangements will strengthen the stability of indemnity provision which will provide assurance for patients in relation to pre-April 2019 clinical negligence claims for redress. Furthermore, there will be no additional cost for GPs or MDOs as a result of the introduction of the ELS.

7.7 The ELS arrangements will also ensure that GPs in Wales are not treated at a disadvantage relative to GPs in England where ELS arrangements are also being introduced. The ELS for Wales, which will be aligned with the ELS in England, will also help to ensure there is no negative impact on cross border activity in terms of GP recruitment, which could be the case if Wales' ELS arrangements were not introduced, or if arrangements in Wales differ from those in England.

Costs of operating the ELS

7.8 The handling of the ELS claims up until April 2021 or earlier if agreed with an individual MDO will be undertaken by the MDO and will be part of the agreement with Welsh Government. Handling of the ELS claims after April 2021 (or earlier if agreed with an MDO) will be undertaken by NHSWSSP – LARS.

7.9 The Welsh Government does not anticipate any additional costs for NHSWSSP - LARS as a result of the ELS that would be greater than the operational costs paid to MDOs during the interim period of management.

8. Competition Assessment

8.1 These Regulations have no effect on charities and/or the voluntary sector.

8.2 A Competition Assessment has been undertaken to assess the potential impact of these Regulations. The results of a filter test is shown below.

8.3 Prior to considering the Competition Assessment, it must be re-stated that the National Health Service (Existing Liabilities Scheme for General Practice) (Wales) Regulations 2020 will affect only those MDOs who have concluded an agreement with the Welsh Ministers in respect of existing liabilities. If an MDO does not conclude such an agreement then there is no effect of the Regulations

on their GP members. The Competition Assessment Filter should be considered in this light.

Question	Answer: Yes or No
Q1: In the market(s) affected by the new regulation, does any firm have more than 10% market share	Yes.
Q2: In the market(s) affected by the new regulation, does any firm have more than 20% market share?	Yes.
Q3: In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share?	Yes.
Q4: Would the costs of the regulation affect some firms substantially more than others?	No.
Q5: Is the regulation likely to affect the market structure, changing the number or size of firms?	No.
Q6: Would the regulation lead to higher set-up costs for new or potential suppliers that existing suppliers do not have to meet?	No.
Q7: Would the regulation lead to higher ongoing costs for new or potential suppliers that existing suppliers do not have to meet?	No.
Q8: Is the sector characterised by rapid technological change?	No.
Q9: Would the regulation restrict the ability of suppliers to choose the price, quality, range or location of their products?	No.

9. Post implementation review

9.1 From April 2021, an annual report will be produced and submitted to the relevant Assembly Committee. The report will cover the technical operation of

the FLS and the ELS and will be informed by GPs and other key stakeholders, medical defence organisations, NHS Wales and NHS Wales Shared Services Partnership - Legal and Risk Services, who operate the FLS and will take over claims handling of the ELS in line with ELS arrangements between Welsh Government and medical defence organisations.

9.2 The annual report will also outline the ELS arrangements agreed between Welsh Government and medical defence organisations and the way in which the Scheme has been operationalised together with a financial impact of the ELS arrangements, subject to adhering to confidentiality agreements.