

**EXPLANATORY MEMORANDUM TO  
THE NATIONAL HEALTH SERVICE (CLINICAL NEGLIGENCE SCHEME)  
REGULATIONS 2015**

**2015 No. 559**

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

**2. Purpose of the instrument**

2.1 These regulations consolidate and revoke the National Health Service (Clinical Negligence Scheme) Regulations 1996 and all amending regulations (the 'CNS Regulations'). The Clinical Negligence Scheme is a statutory indemnity scheme, administered by the NHS Litigation Authority (NHS LA) on behalf of the Secretary of State, which provides cover (through the pooling of annual contributions from member bodies) for clinical negligence compensation claims brought against member bodies that perform functions in relation to the health service.

**3. Matters of special interest to the [Joint Committee on Statutory Instruments or the Select Committee on Statutory Instruments]**

3.1 None

**4. Legislative Context**

4.1 The CNS Regulations had been amended numerous times due to the changing nature of the bodies involved in the NHS since the Clinical Negligence Scheme was first established in 1996. As a result, the regulations have become very complex. To address this, the Scheme regulations are being replaced by these consolidated, modernised Regulations which are intended to be clearer for users. This consolidation and revocation also meets a commitment made by the Department of Health in connection with the Government's 'Red Tape Challenge' to scrap or improve its regulations.

**5. Territorial Extent and Application**

5.1 This instrument applies to England.

**6. European Convention on Human Rights**

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

## 7. Policy background

- What is being done and why

7.1 This instrument consolidates and modernises the CNS regulations and all amendment regulations to date. The CNS Regulations established a scheme whereby eligible bodies make provision for the meeting of qualifying liabilities (as set out in the scheme) to third parties in connection with personal injury or loss arising out of negligence in the carrying out of the members' functions. The Clinical Negligence Scheme for Trusts was established as a way of enhancing clinical negligence handling expertise across the whole of the English NHS. Its creation effectively centralised the way the NHS bodies and, in certain circumstances, private providers of health services, cover their clinical negligence risks, and enables expert and efficient handling of claims and also learning from claims to be shared with a view to reducing harm to patients.

7.2 Regulations 1 and 2 of the instrument cover citation, commencement and application, and interpretation. The Regulations apply to England only. Regulations 3 to 5 state the purpose of the clinical negligence scheme, the bodies which are eligible to be members of it and how they can apply to join the scheme. Regulation 6 deals with the circumstances and manner in which a member may cancel its membership. For administrative reasons, cancellation is only possible by members of at least three years' standing. Regulation 7 allows the Secretary of State to cancel a membership on grounds including non-payment of a member's contribution to the scheme and insolvency. Regulations 8 to 10 stipulate the liabilities to which the scheme applies, including those of members, their sub-contractors and insolvent former members.

7.3 Regulations 11 to 13 specify how payments into the scheme are to be determined and revised, and the duty of members to make contributions. For clarity, Regulation 11(2)(i) refers to "any other factor relating to [a member] or any other member of the Scheme which the Secretary of State considers relevant" as one of the elements he may have regard to when determining each member's payment into the scheme each year. This takes account of the risk-pooling nature of the scheme which means that every member's actions can potentially affect every other member's contributions.

7.4 Regulations 14 to 19 deal with payments out of the scheme in respect of the liabilities of members and, in some circumstances, former members, exclusions, and the power to make payments on account. Regulation 14(4) states that "any liability of a member which falls to be met after the member gives notice of cancellation...but before membership has ceased is excluded from 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 a notice" which is intended to ensure that a member cannot exert undue pressure with regard to settling claims which would not normally have

settled between these dates and thus benefit from such settlement having been achieved before the date of departure.

7.5 Regulations 20 to 23 set out requirements relating to the provision of information, directions and guidance, revocations, savings and transitional provisions.

- Consolidation

7.6 The CNS Regulations were identified as part of the Government's 'Red Tape Challenge' as being complex due to the number of amendments and requiring consolidation to ensure that the law is clear and easy to understand. The Red Tape Challenge gave business and the general public the opportunity to challenge the Government to get rid of or improve burdensome regulations, to boost business and economic growth and to save taxpayers money. The Red Tape Challenge put a 'spotlight' on different areas of regulation in turn collecting comments from the public and putting proposals together for regulatory reform.

- Secretary of State Duties

7.7 The Department has considered the Secretary of State's duties as set out in the National Health Service Act 2006 (as amended by the Health and Social Care Act 2012) and considers that this instrument is consistent with the Secretary of State's duty to promote comprehensive health service, by setting out how he will exercise his function, conferred by the Act, to establish a scheme for meeting the losses and liabilities of certain health service bodies. The Department considers that the other duties are not specifically relevant in relation to this instrument.

## **8. Consultation outcome**

8.1 Given that there are no policy changes being introduced by this consolidating instrument, the Department has conducted no formal consultation in connection with its implementation.

## **9. Guidance**

9.1 The Department of Health does not have any general day to day involvement in the administration of the scheme. The NHS Litigation Authority administers the scheme on behalf of the Secretary of State and it publishes guidance on the operation of the scheme in the form of Scheme Rules. These are amended from time to time and are available on the NHS LA's website at:

<http://www.nhs.uk/Claims/Documents/CNST%20Rules.pdf>

Hard copies may be obtained by emailing: [GeneralEnquiries@nhs.uk](mailto:GeneralEnquiries@nhs.uk)  
or by writing to:

NHS Litigation Authority

2nd Floor, 151 Buckingham Palace Road  
London, SW1W 9SZ

## **10. Impact**

10.1 These regulations consolidate rather than amend existing regulation, therefore the impact on business, charities or voluntary bodies is nil.

10.2 The impact on the public sector is also nil.

10.3 An Impact Assessment has not been prepared for this instrument.

## **11. Regulating small business**

11.1 The legislation can apply to small business, however, the regulations' effect is to allow access to a voluntary scheme; they do not place or impose burdens on small business.

## **12. Monitoring & review**

12.1 As this instrument makes provision for the continuation of the existing clinical NHS negligence scheme, there is no measurable outcome anticipated. As the delegated administrator for the scheme, the NHS Litigation Authority will monitor and review the ongoing operation of the schemes as part of its obligation to report and provide advice to the Secretary of State.

## **13. Contact**

Emma Addy at the Department of Health Tel: 0113 254 5970 or email: [emma.addy@dh.gsi.gov.uk](mailto:emma.addy@dh.gsi.gov.uk) can answer any queries regarding the instrument.