EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (CLINICAL NEGLIGENCE SCHEME) AMENDMENT REGULATIONS 2013

2013 No. 497

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 primarily make provision to extend membership eligibility of the Clinical Negligence Scheme for Trusts (CNST), a statutory indemnity scheme established under section 71 of the NHS Act 2006 in the NHS (Clinical Negligence Scheme) Regulations 1996 ("the 1996 Regulations"). This scheme covers clinical negligence liabilities arising from the carrying out of the members' functions with regards to the NHS.

2.2 The Regulations also make other amendments to way the scheme is administered, including extending the range of clinical negligence liabilities that are covered, new provisions on terminating membership and for clinical negligence cover to continue once membership has terminated in certain circumstances, provisions around the insolvency of members, and revisions to the way that scheme contributions are handled.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

4. Legislative Context

4.1 Given the increasing plurality of provision within the NHS, and the consequent promotion of competition to improve services, restricting membership of the CNST to NHS bodies may give rise to competition issues. These regulations therefore seek to create a fairer playing field between providers by removing the potential for such issues to arise. This is also in line with the Secretary of State's duty to report on and review the treatment of NHS health care providers under section 1G of the NHS Act 2006.

5. Territorial Extent and Application

5.1 This instrument applies to England.

6. European Convention on Human Rights

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

7. Policy background

7.1 CNST was established by the 1996 Regulations as a way of enhancing clinical negligence handling expertise across the whole of the English NHS. The creation effectively centralised the way the NHS bodies indemnify their clinical negligence risks. Changes in NHS provider policy have seen an increasing amount of healthcare provision within the NHS now being delivered by non-NHS bodies, such as commercial providers, social enterprises and local authorities. However, membership of CNST remained restricted to NHS bodies prior to these regulations being made.

7.2 Given the increasing range of health service providers in the NHS, the policy decision was taken in 2006 to allow non-NHS bodies access to membership of CNST, although primary legislation was required to allow this to happen. Provisions were enacted in the Health and Social Care Act 2008 to amend section 71 of the NHS Act 2006 to enable membership of section 71 schemes to be widened.

7.3 However, prior to the changes to primary legislation being in force, amendments were made to the 1996 Regulations as an interim solution to allow some non-NHS bodies (who provide NHS services) to benefit from the cover of CNST indirectly through the commissioning PCT's membership of the scheme. This is not a satisfactory solution on a longer term basis as it effectively transfers the risk from the provider to the commissioner rather than leaving the risk sitting appropriately and directly with the provider. The changes made by these Regulations therefore regularise this position by allowing certain non-NHS bodies who are providing NHS services pursuant to arrangements made, directly or indirectly, with the NHS Commissioning Board, a clinical commissioning group or a Special Health Authority, to become members in their own right, to contribute directly to the scheme to cover their own risks.

7.4 Section 1G of the NHS Act 2006 places a specific duty on the Secretary of State to report on and review the treatment of NHS health care providers. It is therefore right that in meeting this duty, the Department responds to specific concerns to ensure that the range of providers are treated fairly in respect of the CNST.

7.5 Given that there are already satisfactory indemnity arrangements in place for providers in primary care, the scheme will not be available to non-NHS bodies in respect of NHS services provided through primary care contracting arrangements, including primary medical, dental and ophthalmic services, and pharmaceutical and local pharmaceutical

services. The Department is aware of a potential issue relating to availability of access to indemnity for primary medical services out of hours provision so this particular aspect is under review.

7.6 These Regulations also amend the 1996 Regulations to address the issue of increasingly complex care pathways involving multiple healthcare providers. It is necessary to revise the scheme to provide a means of covering potentially the whole of a care pathway within the NHS. Otherwise, a claimant could be in the position where they pursue a claim against multiple healthcare providers potentially all with different indemnifiers. To this end, these Regulations amend the liabilities that are covered by CNST so that, for the purposes of the scheme, certain of the clinical negligence liabilities of a provider member's sub-contractors are treated and dealt with as though a liability of the member. The intention is to provide more positive and timely outcomes for claimants and improve the sub-contracting carried out by members.

7.7 CNST also does not generally provide on-going cover for clinical negligence liabilities once a member leaves the scheme. The Department does not believe this is desirable in future, given that smaller providers will be eligible to join the scheme and this will make the membership of the scheme more fluid and subject to regular change. The Regulations therefore amend the scheme so that if a member wishes to leave the scheme but to have ongoing cover under the scheme for clinical negligence liabilities incurred prior to its membership terminating (but which have not fallen to be met whilst it is a member), the member may agree with the Secretary of State to make additional payments to the scheme to enable this to happen.

7.8 The Regulations also amend the 1996 Regulations to deal with the insolvency of certain scheme members. Specifically, these new provisions provide that certain liabilities of certain non-NHS bodies which provide NHS services pursuant to direct arrangements made with the NHS Commissioning Board, a clinical commissioning group or a Special Health Authority, and whose membership of the scheme is terminated as a result of insolvency, are to be treated as the liabilities of whichever of the Board, a clinical commissioning group or Special Health Authority it made those arrangements with. As these claims would be recorded on the claims history of the member that is the commissioner, this should encourage commissioners to be more rigorous in their commissioning and increase protections for patients in the event of a provider insolvency. The 1996 Regulations are also amended to provide that the Secretary of State may terminate, with immediate effect, the membership of a member which is a non-NHS body providing NHS services under arrangements made with the Board, a clinical commissioning group or a Special Health Authority if that member becomes insolvent or is no longer eligible to be a member (e.g. because the arrangement under which they provide NHS services

has come to an end).

7.9 The NHS Litigation Authority ("NHS LA")(which administers the scheme on behalf of the Secretary of State) Industry Review recommended that the Department review barriers to scheme exit. In particular, it was identified that much of the existing membership found the current minimum twelve month notice period required to terminate membership to be invidious. Following discussions with stakeholders, we have identified that the NHS LA could continue to operate the scheme with a seven month notice period. This should provide a stronger incentive for members to look around the market to get the best indemnity product for their patients, and encourage the NHS LA to strive for producing the most efficient indemnity product for the NHS. These Regulations therefore make amendments to the 1996 Regulations to change when contributions must be notified to members to reflect the reduced termination notice period.

7.10 The Department is currently considering consolidation of a range of statutory instruments for which it is responsible as part of the wider Red Tape Challenge and 'One In One Out' initiative across Government. This has resource implications for the Department but we would expect that any further substantive changes to these particular regulations will be through consolidation rather than amendment.

8. Consultation outcome

8.1 Ever since the Department took powers in the Health and Social Care Act 2008 that allowed section 71 schemes to be extended to non-NHS bodies, the Department has been engaging with stakeholders to develop proposals to effect this. However, wider policy reviews that could have specifically affected reforms to CNST have delayed implementation. These include:

- The Department of Health's Review of its Arms' Length Bodies,
- Equity and Excellence: Liberating the NHS, which resulted in the current NHS reforms that are being implemented through the Health and Social Care Act 2012, and
- The Industry Review of the NHS LA.

8.2 Following these reviews, it has now been possible to implement the policy to widen membership eligibility of the scheme. These regulations were specifically developed through an engagement exercise with health regulators, mutual and commercial indemnity market, healthcare bodies (both private and public sector), and patient and claimant representative organisations, with broad agreement reached on all the policy proposals.

9. Guidance

9.1 The Department of Health does not have any general day to day involvement in the administration of the scheme. As the NHS LA administers the scheme on behalf of the Secretary of State, it publishes guidance on the operation of CNST 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.nhsla.com/Pages/Home.aspx.

10. Impact

10.1 The impact on business, charities or voluntary bodies is thought to be broadly nil as the scheme provides an alternative way of indemnifying clinical negligence risks in the NHS and the cover provided is not comparable to insurance. We expect non-public sector providers to choose from the range of products across the market, and accept that CNST, which does not provide the same risk transfer as insurance, may be considered unsuitable by some providers.

10.2 The impact on the public sector is cost neutral, as the scheme is wholly funded by its membership.

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

11. Regulating small business

11.1 The legislation applies to small business. However, the regulations contain enabling provisions that allow access to a voluntary scheme; they do not place or impose burdens on small business.

12. Monitoring & review

12.1 As the operational administrator for the scheme, the NHS LA will monitor the reforms and keep them under review as part of its on-going obligation to provide the Secretary of State with advice on the operation of the scheme. However, given the general three-year period in which claims can be made from the date of incident, we do not expect the NHS LA to develop an informed view of the reforms until at least April 2018.

13. Contact

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