EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (CLINICAL NEGLIGENCE SCHEME) AMENDMENT (NO.2) REGULATIONS 2006

2006 No. 3087

1. Introduction

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

2. Description

2.1 The Clinical Negligence Scheme for Trusts (CNST) is a scheme set up to allow NHS bodies to pool the risks of clinical negligence liabilities. These Regulations extend the scope of the scheme to include certain clinical negligence liabilities incurred by third parties when engaged by a Primary Care Trust (PCT) to provide NHS services, which immediately before that engagement, the PCT was providing itself.

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

3.1 This statutory instrument is to the same effect as, and replaces, the National Health Service (Clinical Negligence Scheme) (Amendment) Regulations 2006 (S.I.2006/2390) ("the Amendment Regulations 2006"). This instrument is being made following the 37th Report of 2005-2006 from the JCSI reporting the Amendment Regulations 2006 for failure to comply with *Statutory Instrument Practice*[1].

3.2 In the Department's memorandum to the JCSI, the Department acknowledged its failure, though an oversight, to follow the required procedure and proposed that it would make this instrument to replace the Amendment Regulations 2006 as soon as possible. This instrument merely replaces the Amendment Regulations 2006 with the defect remedied. The substance of this instrument matches the Amendment Regulations 2006 which have already been considered by the JCSI . The 21-day rule is therefore being breached in order that those bodies whose clinical negligence liabilities are brought within the CNST by the extension of that scheme will have certainty that these liabilities are covered by the CNST.

3.3 This instrument is being issued free of charge to all known recipients of the Amendment Regulations 2006.

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[1] The guide to the preparation and making of statutory instruments and the parliamentary procedures relating to them, published by the Cabinet Office. The full text of Statutory Instrument Practice is available on the HMSO website www.hmso.gov.uk//services/si_practice.htm

4. Legislative Background

4.1 Section 21 of the National Health Service and Community Care Act 1990 ("the 1990 Act") provides that the Secretary of State may make regulations (with the consent of the Treasury) which establish a scheme for specified bodies to meet:

(a) expenses arising from any loss of or damage to their property; and
(b) liabilities to third parties for loss, damages or injury arising out of the carrying out of the functions of those bodies.

4.2 A scheme to cover clinical negligence liabilities – known as CNST – was established by the National Health Service (Clinical Negligence Scheme) Regulations 1996 (S.I. 1996/251 as amended)

5. Extent

5.1 These Regulations apply to England only.

6. European Convention on Human Rights

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

7. Policy Background

7.1 CNST exists to provide a fair and cost-effective means of handling clinical negligence claims against NHS bodies in England and also to provide risk management guidance, so that adverse incidents and hence claims are reduced in number. CNST contributions are significantly lower than the equivalent commercial insurance premiums.

7.2 Under the 1990 Act, membership of schemes such as CNST is limited to NHS bodies, the Healthcare Commission and the Health Protection Agency. Membership of CNST is limited, by the regulations establishing the Scheme, to:

(a) NHS bodies and the Health Protection Agency; and

(b) the clinical negligence liabilities of those bodies.

7.3 The Regulations include as liabilities which can be covered by CNST the clinical negligence liabilities of certain third parties who have been engaged to provide services to a PCT which is a CNST member and whose liabilities therefore arise from the carrying out of the functions of that PCT. The bodies whose liabilities are brought within the Scheme are those who:

(a) have taken over a service which was previously directly provided by the PCT itself. This would apply for example where a PCT, which

was currently providing nursing services, decided to split its provider and commissioner functions and arrange for services to be provided by a third party, for example a social enterprise; and

(b) satisfy the body running CNST that they meet the requirements which have to be met by NHS bodies when they become members of the Scheme. This will, amongst other things, require the organisation to demonstrate that they comply with NHS Litigation Authority (NHSLA) risk management standards (ensuring they will not be a higher risk than NHS organisations).

[The extension does not apply to GP services or primary dental services as they have other arrangements in place for meeting clinical negligence liabilities].

7.4 The amendment ensures that NHS patients receiving services from the third parties covered by the extension will continue to have the benefit of a uniform claims experience and will not be disadvantaged in the claims process by the change in service provider.

7.5 The National Health Service Litigation Authority (NHSLA), which administers the CNST Scheme on behalf of the Secretary of State, currently meets centrally the costs of clinical negligence when they arise. It covers the costs of these claims by the contributions which it levies from the Scheme members Because the third party whose liabilities are brought within the Scheme cannot be a member of the Scheme itself the Regulations provide for the Scheme to treat liabilities of the third party as if they were liabilities of the PCT which has arranged provision of the services. Thus, when assessing the level of that PCT's contribution to the Scheme, the NHSLA will take account both of the PCT's own liabilities and any relevant liabilities of third parties which are to be covered by their membership. It is intended that the contract between the NHS body and the provider should commit the PCT to making such contributions which will be reflected in a reduction in the contract price.

7.6 Greater diversity in provision of NHS care means that NHS patients may increasingly be treated outside traditional NHS settings. In the longer term the Government intend to amend the primary legislation to allow a wider range of providers of NHS services to become members of schemes such as CNST. These Regulations are intended as an interim measure pending such changes being considered by Parliament.

8. Impact

8.1 No Regulatory Impact Assessment has been prepared because there is no regulatory impact on any part of the private or voluntary sector. There are no implications for the Exchequer.

9. Contact

9.1 Any enquiries about the contents of this memorandum should be addressed to:

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