EXPLANATORY MEMORANDUM TO

THE PRIMARY OPHTHALMIC SERVICES AMENDMENT, TRANSITIONAL AND CONSEQUENTIAL PROVISIONS REGULATIONS 2008

2008 No. 1700

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 These regulations make technical and consequential amendments. They follow the laying of the:
 - General Ophthalmic Services Contracts Regulations 2008
 - Primary Ophthalmic Services Regulations 2008
 - National Health Service (Performers Lists) Amendment and Transitional Provisions Regulations 2008
 - Primary Ophthalmic Services Transitional Provisions Regulations 2008
- 2.2 The Primary Ophthalmic Services Amendment and Consequential Provisions Regulations 2008 amend existing regulations specified in Schedule 1 to correct and update references in them and revoke, in Schedule 2, the National Health Service (General Ophthalmic Services) Regulations 1986 and various Regulations amending those Regulations which are superseded, in consequence of the Regulations set out above, and as such are purely technical.

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

Paragraph 28 of Schedule 1 remedies the issue raised by the Committee in correspondence with the Department in relation to the Primary Ophthalmic Services Regulations 2008 (S.I. 2008/1186) and which the Department undertook to address by 1st August (see the 21st report of the Committee, printed 11th June 2008). The Committee pointed out that "notice of entitlement" was not defined in those Regulations. Paragraph 28 adds such a definition.

4. Legislative Background

These instruments are made under powers in sections 16CD, 28WD and 28X(2A) in the National Health Service Act 1977 and section 43 of the Health Act 2006.

5. Territorial Extent and Application

These instruments apply to England.

6. European Convention on Human Rights

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

7. Policy background

It may be helpful to set out the purpose is of the regulations which give rise to the need for the Primary Ophthalmic Services Amendment and Consequential Provisions Regulations 2008.

General Ophthalmic Services Contracts Regulations 2008, Primary Ophthalmic Services Regulations 2008 and the National Health Service (Performers Lists) Amendment and Transitional Provisions Regulations 2008 and the Primary Ophthalmic Services Transitional Provisions Regulations 2008

- 7.1 The regulations being introduced from 1 August 2008 (the General Ophthalmic Services Contracts Regulations 2008, the Primary Ophthalmic Services Regulations 2008 and the National Health Service (Performers Lists) Amendment and Transitional Provisions Regulations 2008) implement primary legislation which allows Primary Care Trusts (PCTs) to enter into contracts with all suitable providers to provide the service. These regulations follow the format of the medical and dental contracts and introduce provider/performer arrangements for the provision of NHS funded sight tests.
- 7.2 However, the ophthalmic regulations differ in important respects and have not simply followed the model previously used. Importantly, contracts for ophthalmic services provide no guarantee of work, i.e. PCTs are not commissioning specific activity, but simply allow, as is the current arrangement, an optical business to make itself available to people who are eligible for NHS funded sight tests. Having a contract merely means that if an NHS patient chooses to seek a sight test from a contractor, that contractor is entitled to be paid by the PCT. Contractors maximise their business by encouraging as many NHS patients as possible to choose to avail themselves of their services. The contractual regime does not change this basic element of the system which, in our view, works well and Ministers did not want to alter fundamentally the system, but to make improvements on the current basis.
- 7.3 The main change is to remove restrictions on who may contract to provide NHS funded sight tests. Currently only optometrists, ophthalmic medical practitioners and corporate bodies registered with the General Optical Council may be on the ophthalmic list as providers. This restrictive regime no longer reflects the reality of how sight tests are provided. Currently businesses owned by dispensing opticians and lay people are not able to contract directly with the NHS but must have an arrangement with an optometrist or ophthalmic medical practitioner who is able to contract with the NHS and effectively acts as a "front man" for the business. Under the new regulations, this restriction is removed and any suitable provider may contract with the NHS for the

provision of NHS funded sight tests. This will simplify arrangements for businesses owned by dispensing opticians and lay people.

- 7.4 The transition from current arrangements to the contracting regime is largely automatic. Current contractors, with the exception of those who were entered onto the ophthalmic list in error or against whom there are disciplinary procedures will have a right to a contract. They will not have to apply and undergo an assessment of their suitability, but simply notify their PCT that they wish to have a contract and confirm that the information held by the PCT is up to date and accurate, or update it, if it is not, and then they will be awarded a contract.
- 7.5 In respect of performers, there is again an automatic process. Clinicians who are currently on a PCT supplementary list will be automatically transferred to that PCT's performers list without the need for an application or assessment. For clinician business owners there will be a need for them to be entered onto a performers list. Where they only operate in one PCT area, they will simply be included in that PCT's performers list. If they have businesses in more than one PCT area then the clinician business owner will be able to choose on which performers list they want to be entered from those held by PCTs in which their business provides services.
- 7.6 Entitlement of patients to NHS funded sight tests is unchanged by the new regulations and eligible patients will continue to be able to present to a local contractor of their choice as they do now. For the patient the changes being made should be invisible.
- 7.7 The fee structure is also unchanged and the service continues to be demand led and not locally commissioned. There is currently no shortage of qualified professionals (optometrists and ophthalmic medical practitioners) to undertake the clinical work and no shortage of businesses wishing to contract in what is a highly competitive area.
- 7.8 The regulations also create a list of local performers of NHS sight tests on similar lines to those that exist for medicine and dentistry. In common with regulations governing NHS primary medical and dental services, anybody who wishes to perform clinical services under a General Ophthalmic Services contract must be on a Primary Care Trust ophthalmic performers list. These arrangements replace arrangements under the National Health Service (General Ophthalmic Services Regulations) 1986 as amended.
- 7.9 The listing regime includes provisions in relation to the conditional inclusion in a list, suspension from the list, contingent removal and disqualification. A national disqualification can be determined by the Family Health Services Appeal Authority established by section 169 of the 2006 NHS Act.

- 7.10 The NHS General Ophthalmic Services Contracts Regulations 2008 set out required terms for contracts and also lay down who may not hold contracts. It includes provision whereby the may disqualify someone from having a contract to provide these services.
- 7.11 The regulations do not affect the services available to the public. Entitlement to NHS funded sight tests of all those currently eligible and this entitlement is set out in the Primary Ophthalmic Services Regulations 2008, which essentially restates the existing position.
- 7.12 The Primary Ophthalmic Services Transitional Provisions Regulations 2008 provide for Primary Care Trusts to act in advance of the main regulations coming into to force in order to allow work to proceed to establish the new arrangements.
- 7.13 The regulations have been extensively consulted on with the representatives of the profession who have indicated that they are content with the regulations. Consultees supported the primary aim of the changes which was to remove restrictions on who may contract with the NHS to provide NHS funded sight tests. Changes were made to draft regulations to recognise the specificity of ophthalmic services when there was a clear case for regulations to differ from other areas of NHS primary care. Consultation took place from August 2007 until April 2008 and included meetings with representatives of the profession as well as written comments.
- 7.14 We have also worked closely with them on developing model contracts, which include all of the mandatory clauses which follow from regulations, and the recommended clauses. We have recommended these model contracts to the NHS and the optical bodies have recommended them to their members. This is intended to help avoid need for costs to be incurred by PCTs and providers in drafting and agreeing the detail of contracts.

The Primary Ophthalmic Services Amendment and Consequential Provisions Regulations 2008

- 7.15 The Primary Ophthalmic Services Amendment and Consequential Provisions Regulations 2008 make various amendments following upon the package of measures referred to above and are purely technical.
- 7.16 The regulations allow for the continuation of work which had begun under the National Health Service (General Ophthalmic Service) Regulations 1986 as amended, that were not dealt with by 31 July 2008, in relation to investigation of outstanding complaints, complaints made after 31 July 2008 relating to

general ophthalmic services, recovery of overpayments, remuneration of ophthalmic practitioners, service or documents and records.

- 7.17 These regulations also make transitional arrangements in respect of the National Health Service (Service Committees and Tribunal) Regulations 1992 to cover matters such as: cases where no decision has been taken; referrals to investigating disciplinary committees; and determinations of a PCT or the Secretary of State before 1 August 2008. The regulations also cover arrangements in respect of determinations of a PCT on or after 1 August 2008, appeals to the Secretary of State against determinations made before 1 August 2008 and functions of Local Optical Committees in relation to matters which had not been determined by 1 August 2008.
- 7.18 These regulations make minor and consequential amendments to legislation to correct and update references in those instruments in preparation for the coming into force of the earlier package of Regulations.

8. Impact

- 8.1 An impact assessment was undertaken in respect of the new regulations and the conclusion of the assessment was that costs on business would be less than the threshold of £5 million, which is required for a full impact assessment. Technical and consequential amendments have no additional impact and, indeed, are intended to make for a smooth transition by ensuring that work which started before 1 August 2008 under regulations being revoked continues under the new regulations.
- 8.2 We do not consider that these Regulations have any additional implications for equality.

9. Contact

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