

**EXPLANATORY MEMORANDUM TO THE  
NATIONAL HEALTH SERVICE (GENERAL OPHTHALMIC SERVICES  
SUPPLEMENTARY LIST) AND (GENERAL OPHTHALMIC  
SERVICES AMENDMENT AND CONSEQUENTIAL  
AMENDMENT) REGULATIONS 2005**

**2005 No.480**

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

This memorandum contains information for the Joint Committee on Statutory Instruments/the Merits Committee of the House of Lords.

2. **Description**

- 2.1 The primary purpose of the measure is to provide increased protection to the public and meet commitments made following the Shipman Enquiry by ensuring that all ophthalmic opticians and ophthalmic medical practitioners involved with General Ophthalmic Services are listed with PCTs.

- 2.2 The regulations also strengthen regulation of mobile optical services and create a level playing field between practices with community premises and national mobile practices. The regulations also allow for direct referral by ophthalmic opticians to secondary care to improve patient service and shorten the patient's journey into secondary care.

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

- 3.1 None.

4. **Legislative Background**

- 4.1 These regulations amend the National Health Service (General Ophthalmic Service) Regulations 1986, the National Health Service (Optical Charges and Payments) Regulations 1997 and the Sight Testing (Examination and Prescription) (No 2) Regulations 1989.

5. **Extent**

- 5.1 This instrument applies to England.

6. **European Convention on Human Rights**

- 6.1 Not applicable.

7. **Policy background**

- 7.1 The Health and Social Care Act 2001 provides for regulations to be laid for supplementary lists to be maintained of primary care professionals who assist contractors in the provision of services. These regulations have been introduced for doctors (though they have since been replaced by medical performers lists) and dentists and we are now seeking to introduce supplementary lists for ophthalmic opticians.
- 7.2 The primary purpose of the measure is to provide increased protection to the public and meet commitments made following the Shipman Enquiry by ensuring that all ophthalmic opticians and ophthalmic medical practitioners involved with General Ophthalmic Services are listed with PCTs.
- 7.3 The regulations also strengthen regulation of mobile optical services and create a level playing field between practices with community premises and national mobile practices. The regulations also allow for direct referral by ophthalmic opticians to secondary care to improve patient service and shorten the patient's journey into secondary care.

## **8. Impact**

- 8.1 A Regulatory Impact Assessment is attached to this memorandum.
- 8.2 The impact on the public sector is in terms of constructing a new list of optometrists and ophthalmic medical practitioners to be held by Primary Care Trusts. There will also be a need to transfer practitioners incorrectly placed on the Ophthalmic List and consider applications from practitioners to enter the Supplementary List. This activity is mainstream PCT work and parallels what they already do in respect of medicine and dentistry. Staff are already in place and it is not anticipated that additional staff will be required. Four months is being allowed for implementation, which provides PCTs with time to plan for any additional work in tidying up lists.
- 8.3 Primary Care Trusts will also have to consider applications from providers of mobile optical services and receive more detailed notifications of business to better regulate this area of activity.

## **9. Contact**

Derek Busby at the Department of Health on telephone number 020 7972 3992 or e-mail [Derek.Busby@dh.gsi.gov.uk](mailto:Derek.Busby@dh.gsi.gov.uk) can answer any queries regarding the instrument.

## FINAL FULL REGULATORY IMPACT ASSESSMENT

### 1. Title of Proposal

The National Health Service (General Ophthalmic Services Supplementary List) and (General Ophthalmic Services Amendment and Consequential Amendment) Regulations 2004.

### 2. Purpose and intended effect of measure

#### (i) The objective

The Government objective is to provide increased protection to the public, meet commitments made in response to the Shipman Case, and ensure that all practitioners making arrangements to provide NHS General Ophthalmic Services are listed with Primary Care Trusts (PCTs).

We also want to:

- allow ophthalmic opticians practices with community premises and mobile practices (i.e. practices without premises in an area) to provide the full range of mobile services to individual's homes and residential and day centres to increase provision to patients who are unable to attend a community practice;
- allow ophthalmic opticians providing General Ophthalmic Services to refer patients directly to secondary care (NHS hospitals and Treatment Centres) to improve patient service and shorten the patient's journey into secondary care.

#### (ii) The background

The Shipman Enquiry reported in 2002 but the Government acted before then to take powers to ensure that medical, dental, ophthalmic and pharmaceutical lists held by PCTs included all practitioners who work under NHS arrangements in primary care.

The Health and Social Care Act 2001 provides for regulations to be laid for supplementary lists to be maintained of primary care professionals who assist contractors in the provision of services. These regulations have been introduced for doctors and dentists and these regulations introduce supplementary lists for ophthalmic opticians and ophthalmic medical practitioners who will be employed by contractors on the, already existing, ophthalmic list.

The current ophthalmic list was created to provide for listing of individual practice owners and corporate bodies enrolled with the General Optical Council as in businesses as ophthalmic opticians (optometrists). To be entered onto the ophthalmic list a contractor must be able to meet the General Ophthalmic services Terms of Service which include provision of premises, equipment and the keeping of records.

The supplementary list introduced by these regulations will be for individual practitioners who undertake sight tests but who are unable to wholly meet the NHS Terms of Services; usually this would be employed professionals who use their employers' premises, equipment and have records kept for them.

Contractors i.e. practice owners and companies enrolled with the General optical Council are required to be on the ophthalmic list of each PCT where they provide

General Ophthalmic Services. Their assistants, whether employees or deputies, are only required to be listed under their names when they are regularly engaged. However, in practice most PCTs appear to have placed all ophthalmic opticians on their ophthalmic list and to require fresh applications from each ophthalmic optician who wishes to work in their area.

General Ophthalmic Services can currently only be provided at individual's homes by providers with community premises in the area and not by mobile practices. There are a number of companies who have been set up to provide mobile optical services and this restriction reduces the scope for people who are unable to get to a practice to obtain services. Current regulations on mobile services are unclear and do not allow the NHS to effectively monitor to ensure appropriate standards are being met and clearer regulations are proposed to allow this.

Currently ophthalmic opticians providing General Ophthalmic Services must refer a patient to their GP who will then make a referral to hospital.

### (iii) Risk assessment

The measure introduces arrangements which will ensure that all providers (individual and company) of General Ophthalmic Services and the individuals employed by them will be listed with PCTs. Currently there are providers who are not listed with PCTs and therefore are operating outside of the legal framework which means that PCTs have no legal recourse in respect of them. This creates a problem in respect of oversight of clinical standards and controlling potential fraud. These regulations provide a framework in which the public can be confident that the NHS is regulated properly and all ophthalmic opticians listed with PCTs to provide assurance that they are suitable to practice under NHS arrangements.

Maintaining current regulations unchanged would mean that providers who have been operating as General Ophthalmic Services providers outside regulations would have to stop which would have consequences for their business and patients.

The changes in respect of mobile practices create clearer, more effective regulation of an area, which has been the cause of concern from the NHS and NHS Counter Fraud and Security Management Services (NHS CFSMS) and will, for the first time, require providers to be specifically listed as providers of domiciliary general ophthalmic services. NHS CFSMS figures show that optical patient fraud in 2003/4 amounted to £10.170 million. Presently mobile service providers are not required to be listed as such and therefore no assessment is made of their suitability or the adequacy of their equipment. In addition, they are not required to notify in any detail of the work that they plan to do in residential and day centres and the NHS have difficulty judging whether sight tests have been carried out in accordance with regulations.

Maintaining current arrangements on referral following a sight test provided under General Ophthalmic Services would mean that patients would continue to be referred through their General Practitioner. This would maintain an extra step in their passage to secondary care and an extra task for General Practitioners.

### **3. Options**

The following 2 options were considered:

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|----------|--|
| Option 1 | Leave things unchanged   |
| Option 2 | Introduce legislation to establish supplementary lists for ophthalmic opticians who assist in the provision of General Ophthalmic Services and which are held by Primary Care Trusts. Require that any |

practitioner wishing to assist in the provision of General Ophthalmic Services be on a supplementary list.

## **Benefits**

### **Option 1**

#### *Economic*

PCTs would not have to construct a new list and transfer practitioners wrongly placed on the ophthalmic list, which would save administrative work.

#### *Social*

There are no additional benefits to patients from continuing with current arrangements.

#### *Environmental*

There are no environmental benefits from continuing with current arrangements.

### **Option 2**

#### *Economic*

Supplementary Lists will allow ophthalmic opticians to assist in other parts of the country without the need for a fresh application in each area. This will smooth business processes and allow national companies to more effectively move staff around to meet particular needs in different areas.

There will also, after the tidying up exercise (see below), be less administrative burden on PCTs as a practitioner on one supplementary list will be able to assist in any PCT area. This will mean that PCTs will no longer consider applications from individuals who wish to work in their areas provided they are on a supplementary list in another area. As these practitioners will be on a supplementary list PCTs will be assured that another NHS body has considered and accepted the practitioner

Newly qualified practitioners will need to be accepted before they are able to practice under NHS arrangements. The draft regulations make provision for application before qualification so that newly qualified practitioners will have a minimal waiting period before they may practice under NHS arrangements.

New provisions allow for a way for providers who are not listed with PCTs and who would, therefore, need to stop providing NHS services to make arrangements with optometrists to continue providing General Ophthalmic Services.

#### *Social*

In respect of the primary measure in these regulations, establishing Supplementary Lists for ophthalmic opticians will ensure that all practitioners working within the NHS have applied to and been accepted by Primary Care Trusts. This will deliver an assurance of standards and provide an assurance of public protection that is currently available to patients in respect of medical and dental services. Like other health professionals, ophthalmic opticians see patients in private settings and are in a position of responsibility and authority and it is essential that the public have confidence that practitioners are properly considered and accepted by the NHS.

Direct referral by ophthalmic opticians to secondary care will enable patients to reach the hospital sector more quickly;

Changes in respect of mobile optical services will create a level playing field between practices with community premises and those without; allow patients who cannot leave home to receive NHS funded sight tests at home from a greater range of providers; and provide clarity and more consistent regulation to allow concerns about potential fraud in this area to be addressed.

#### *Environmental*

There are no environmental benefits from this measure.

### **5. Costs**

#### **Option 1**

##### *Economic*

Practitioners will continue to be asked to apply to PCTs in whose area they wish to work and have to complete forms and obtain references in each case. PCTs will continue to process applications from these applicants with the associated administrative costs.

Costs will be incurred if GPs continue to receive referrals from ophthalmic opticians for patients to be referred onto secondary care. They, or their staff, will see patients the patients and have to send letters to hospitals.

Some existing providers who have not been operating accordance with regulations may not be able to continue as NHS providers with costs to their business and to patients if they felt obliged to seek private sight tests.

##### *Social*

Some existing providers who have not been operating accordance with regulations may not be able to continue as NHS providers with costs to patients who may have to travel further for an NHS funded sight test.

Patients will not benefit from being referred directly to hospital as they will have to go through their General Practitioner, which inevitably increases the time taken as it is an extra step.

Patients will not benefit from increased access to General Ophthalmic services from mobile service providers if regulations are not changed to allow them to undertake such services at individual's homes.

##### *Environmental*

There are no environmental costs from continuing with current arrangements.

#### **Option 2**

##### *Economic*

The NHS will construct and maintain lists and will need to make transfers of practitioners who have been incorrectly placed on the Ophthalmic List and consider applications from practitioners to enter the Supplementary List. This activity is mainstream PCT work and parallels what they already do in respect of medicine and dentistry. Staff are already in place and it is not anticipated that additional staff will

be required. Four months is being allowed for implementation, which provides PCTs with time to plan for any additional work in tidying up lists. The transfer of practitioners incorrectly placed on the ophthalmic list is a “one-off” tidying up exercise.

Some 70% of sight tests are provided by corporate bodies with around 55% estimated as being provided by the four largest companies. The individual ophthalmic opticians employed by these corporate bodies as well as individual practice owners and their employees and locums would all need to be on the Supplementary List. At December 2003 there were 7734 ophthalmic opticians on PCT lists. It is likely that, at most, only a few hundred practising ophthalmic opticians are not on a list. Therefore there will be no costs to businesses in these cases as there will be no requirement to reapply. PCTs will have to make transfers of practitioners incorrectly placed on the ophthalmic list but as indicated above five months is being allowed for implementation so that the task can be done properly and without undue burden and this is a “one-off” exercise.

Where corporate bodies are not on PCT lists they will need to be, if they wish to provide General Ophthalmic services. However, this is an existing requirement and not a new one created by these regulations and therefore costs from such changes do not arise from these measures.

Ophthalmic opticians who are not currently on PCT lists will need to apply if they wish to practice under NHS arrangements. As indicated above this is likely to apply only to a relatively small number of practitioners. There is no charge for applying to join a PCT list but practitioners will need to complete forms and provide references.

#### *Social*

There are no social costs from the proposals.

#### *Environmental*

There are no environmental costs from the proposals.

### **6. Equity and Fairness**

General Ophthalmic Services are provided to defined population groups – under 16 years old, 16-18 and in full time education, over 60 and people with or at risk of diabetes and glaucoma. These people will therefore benefit from a better regulated NHS ophthalmic service. Requirements to be on an ophthalmic list apply to all contractors (individual optometrists, ophthalmic medical practitioners or corporate bodies in business as optometrists) who wish to provide General Ophthalmic Services and PCTs need to ensure that all their contractors are listed.

#### **Rural Proofing**

Allowing providers without fixed premises to provide sight tests under General Ophthalmic Services to individuals’ homes will increase provision and be of benefit to people who are unable to access community premises. However, there are no general access difficulties with optical services.

#### **Race Impact**

The policy has no particular race impact. Optometrists will all have to be listed with PCTs and patients in eligible categories for sight tests provided under General Ophthalmic Services will come from all races.

## **7. Consultation with small business: the Small Firms' Impact Test**

Some 70% of sight tests are provided by corporate bodies with around 55% estimated as being provided by the four largest companies. The remainder of providers will be independent practitioners. However, these regulations do not change which businesses may be on the ophthalmic list. There is some clarification in the regulations in respect of corporate bodies as, currently, the regulations are written in terms of individuals, which is clearly not always appropriate. Companies who are not able to be on the ophthalmic list but wish to be will need to constitute themselves accordingly. However, this is not a consequence of these regulations and would be the position whether they were introduced or not. The new supplementary list will be comprised of individuals and not businesses whether large companies or independents.

The specific requirement for PCTs to consider and list mobile service providers as such is new. Such providers will need to apply to the PCTs where they wish to provide General Ophthalmic Services and there will be a cost in time taken to complete application forms but there is no fee for being listed with a PCT. As this is a new requirement, we are proposing that providers have two months to apply after the regulations come into force and can then continue until their application has been determined or the regulations come into force whichever is the earlier so that service provision is not affected and businesses are not adversely affected.

## **8. Competition Assessment**

These regulations introduce no new requirements, which affect who may be listed with PCTs as providers of General Ophthalmic Services and therefore enter onto the ophthalmic list. However, they do provide a means whereby businesses who are not able to be listed with Primary Care Trusts may work with ophthalmic opticians or ophthalmic medical practitioners who are on lists. This will help to maintain current provision of service and provides a means for entry into this area by providers who are not enrolled with the General Optical Council as being in business as ophthalmic opticians.

The supplementary list which is created by these regulations is for individual practitioners only and not for businesses.

## **9. Enforcement and Sanctions**

The measures require PCTs to construct a new Supplementary List, which is to be published. PCTs must ensure that only practitioners on either the ophthalmic or supplementary lists practice in their areas. Failure to comply with the regulations can lead to PCTs removing either corporate bodies or individuals from their lists, which will mean that they cannot provide ophthalmic services under NHS arrangements.

## **10. Monitoring and Review**

The regulations allow for practices that cannot be listed with PCTs to continue operating through legally binding arrangements with ophthalmic opticians or ophthalmic medical practitioners. These provisions have been included to maintain continuity of service whilst these providers constitute themselves so that they can be listed with PCTs. Primary legislation may be required in the longer term to fully regularise the situation and this will be subject to review by the Department of Health. The Department of Health will work with the NHS Counter Fraud and Security



Management Service to review the effectiveness of new arrangements for mobile optical services providers. The Department of Health is planning a review of General Ophthalmic Services and listing arrangements may be considered within this.

## **11. Consultation**

### i) Within government

The need for Supplementary Lists was established with the passage of the Health and Social Care Act 2001 following the Shipman Enquiry to ensure protection of the public.

### ii) Public Consultation

The Government began consultation with representatives of ophthalmic opticians, corporate bodies in business as ophthalmic opticians and the NHS in December 2003. Draft regulations have been shared, comments considered and changes made to ensure providers concerns are addressed wherever possible. The consultation brought to light that arrangements have grown in practice, which did not meet the existing legal framework. In response to this the new regulations include provisions to bring practice within the law, without damaging the provision of the services or restricting business opportunities. These provisions allow for a new way for providers to make arrangements with the NHS through a registered optometrist, which is not legally possible at present.

## **12. Summary and Recommendation**

We recommend Option 2 i.e. establish supplementary lists for ophthalmic opticians, allow mobile services to provide General Ophthalmic Services to individuals homes and allow ophthalmic opticians to refer directly to secondary care.

<b>Option</b>	<b>Total cost per annum Economic, environmental, social</b>	<b>Total benefit per annum Economic, environmental, social</b>
1 Do nothing.	Practitioners would continue to apply to each PCT where they wish to work with costs to them and PCTs. Patients will not be referred directly to hospitals and GPs will continue to have to process referrals from optometrists. Mobile services will not be able to provide a service to patients in their own homes, which may mean that need, is not met.	PCTs will not have to set up a new list and transfer people currently incorrectly on the ophthalmic list to that list.
2 Establish Supplementary Lists for ophthalmic opticians.	Costs arising from new measures in these regulations are minimal on business. The NHS will construct lists and it is not expected that additional resource will be required	Greater assurance of protection to the public as envisioned following the Shipman Enquiry. Easier movement around the country for ophthalmic opticians on a

	to do this. A “one-off” exercise” to transfer practitioners incorrectly entered on the ophthalmic list to a supplementary list will be necessary.	supplementary list, which will benefit ophthalmic businesses with branches in more than one PCT area. PCTs will not have to consider applications from opticians who wish to work in their areas for short periods of time as they will already be on a supplementary list elsewhere. Patients benefit from direct referral to ophthalmic hospitals which will allow them to access secondary care more quickly. Increased availability of NHS funded sight tests in individuals’ own homes with clearer regulation of service provision to residential and day centres.
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**13. Declaration**

*I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs*

**Signed** .....

**Date**

**ROSIE WINTERTON, MINISTER OF STATE, DEPARTMENT OF HEALTH**

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