

## **EXPLANATORY MEMORANDUM AND REGULATORY IMPACT ASSESSMENT TO**

The National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) (Amendment) Regulations 2009

1. This Explanatory Memorandum and Regulatory Impact Assessment has been prepared by the Community Primary Care Health Services Division and is laid before the National Assembly for Wales in accordance with Standing Order 24.1.

2. **Description**

These Regulations further amend The National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007 to make provision for the making of refunds for prescription charges incurred by patients who are registered with Welsh GPs, but who receive their treatment in secondary care from English NHS Trusts or from the providers of out-of-hours general medical services based in England and; to broaden the list of medical conditions that entitle sufferers to receive exemption from charge to include patients who have been diagnosed as suffering from cancer.

- 3 **Matters of special interest to the Subordinate Legislation Committee**

None

4. **Legislative Background**

This statutory instrument is being made under exercise of the powers conferred by sections 121, 130, 132 and 203 (9) and (10) of the National Health Service (Wales) Act 2006.

This statutory instrument follows the negative resolution procedure.

5. **Purpose and intended effect of the legislation**

Policy Background

***Cross Border refunds***

There are a number of patients who, although registered with Welsh GPs, regularly receive treatment within English NHS Trusts, or from out of hours services based in England. If they are issued with prescriptions following such treatment these will be English prescription forms

(FP10s/ FP10 (HP)) and when taken to a Welsh pharmacy for dispensing the Welsh Regulations provide that they will be required to pay the current prescription charge that is specified in the NHS (Charges for Drugs and Appliances) Regulations 2000 ("the English Regulations"). In addition some patients who attend English NHS Trusts and have no option other than to have their prescription dispensed within that Trust's pharmacy are also subject to the charge in accordance with the English Regulations.

### ***Medical Exemptions and Cancer Patients***

Before the introduction of free prescriptions in Wales they were only free for those people under 25 and over 60 or who were suffering from certain prescribed medical conditions, or for those who were qualified on financial grounds under the NHS Low Income Scheme. This policy was upheld on an England and Wales basis and subsequently rendered otiose for the majority of prescriptions dispensed in Wales when prescription charges were abolished for persons who met the prescribed criteria (in order to benefit from the exemption from payment of the prescription charge the patient must be resident in Wales, registered with a GP who has a contract with an LHB to provide primary medical services and the prescriptions issued under these arrangements must be presented for dispensing to a pharmacy with a contract to provide pharmaceutical services in Wales).

However, in September 2008 the Department of Health announced that from April 2009 patients who have a valid exemption certificate issued by the Secretary of State on the ground that the person is undergoing treatment for cancer, the effects of cancer or the effects of cancer treatments would be added to the list of medical exemptions and would not incur prescription charges in England; provision for the recognition of certificates issued under reciprocal arrangements that may be made in Wales, Scotland and Northern Ireland was also included in the English Regulations

As prescription charges in Wales had already been abolished for patients who meet the prescribed circumstances this amendment does not appear to be of immediate relevance. However, amendments will be required to the Welsh Regulations to maintain the reciprocal arrangements for exemption from charge for prescribed medical conditions in each of the four administrations that have persisted for many years. This means that Welsh patients suffering from the effects of cancer or the treatment of cancer who obtain pharmaceutical services in England, Scotland and Northern Ireland will be entitled to receive free prescriptions provided they have a valid certificate of exemption. Amendments to regulation 9 of the NHS (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007 made by these Regulations makes provision for Local Health Boards to issue a certificate of exemption on behalf of Welsh Ministers.

## Objective

These Regulations seek to address anomalies the current Regulations to:

- Provide a mechanism to issue refunds for prescription charges incurred by patients who are registered with Welsh GPs, but receive their treatment in secondary care from English NHS Trusts, or who receive services of the providers of out of hours general medical services based in England; and
- to broaden the list of medical conditions which entitle sufferers to receive exemption from charge to include patients who have been diagnosed as suffering from cancer.

## 6. **Implementation**

It is intended that these Regulations will come into force on 20 October 2009. If these Regulations were to be annulled then the failure to implement the amendments would mean some patients with a Welsh GP would in certain circumstances, be excluded from the free prescriptions policy in Wales and, in the case of medical exemptions, the parity with other administrations for medical exemptions would be compromised.

## 7. **Consultation**

A consultation has been undertaken and details are included in the Regulatory Impact assessment (RIA) below.

## 8. **Regulatory Impact Assessment**

These Regulations have no impact on the statutory duties (sections 77 -79 GOWA 06) or impose any additional burdens upon the statutory partners (sections 73-75 GOWA 06).

### a) **Options (for achieving the policy objective – as set out in paragraph 5 above)**

#### Option 1 - No regulatory change.

Make no amendments to the principal regulations.

This would not resolve the identified anomalies within the principal Regulations and would not allow patients with a Welsh GP, exemption from prescription charges in certain

circumstances or exemption from charges for patients with a cancer related illness.

#### Option 2 – Regulatory change.

Make the amendments to the principal regulations contained within these Regulations.

This will resolve the identified anomalies as detailed under the objective above.

#### Option 3 – Entitlement Cards for patients

Issuing cards automatically to all Welsh patients who may attend an NHS Trust at some point in the future would be prohibitively costly, possibly open to abuse and arguably unnecessary. Approximately 50% of patients receiving treatment would not have to pay for their English prescription anyway being exempt from the payment of charges under the English Regulations on grounds of age, medical conditions or benefiting from the remission of charges based on entitlement under the NHS low income scheme.

#### b) **Benefits**

There will be improved social and health benefits as a result of the implementation of this statutory instrument.

Option 1: No regulatory change.

In certain circumstances patients with a Welsh GP will still be required to pay for their prescriptions. This may have a social/economic/health effect as some patients may decline to present their prescriptions due to the costs involved.

Option 2: Regulatory change.

Benefits to patients will be achieved directly.

Option 3: Entitlement Cards.

Issuing cards to all patients who may need secondary care treatment in English NHS Trusts would achieve the desired result of exempting patients from prescription charges but be prohibitively expensive and compromised in certain areas.

#### c) **Costs**

There are no foreseen additional costs to the Welsh Assembly Government associated with this legislation. It is likely that costs will be marginal and will be contained from existing baselines.

d) **Competition Assessment**

N/A

e) **Consultation**

NHS Counter Fraud Services, NHS Business Services and Welsh Assembly Government Legal Services were all consulted as part of a risk assessment exercise for implementing this legislation. Parties consulted provided a positive response supporting a unified approach in assessing and approving a mechanism for prescription refunds that was financially viable and proportional to the risk of abuse.

f) **Post implementation review**

The effect of the changes made by these Regulations upon the processes for prescription charges and exemptions will be monitored by officials in the Welsh Assembly Government Health and Social Services Directorate General.

g) **Summary**

There are no costs associated with the implementation of the policy in this legislation. The regulatory option embodied in the Order provides the most cost effective and straightforward option for administering this legislation.