EXPLANATORY MEMORANDUM AND REGULATORY IMPACT ASSESSMENT TO THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL SERVICES) (AMENDMENT) (WALES) REGULATIONS 2009

1. This Explanatory Memorandum and Regulatory Impact Assessment has been prepared by the Community Primary Care Health Services Directorate 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 (Pharmaceutical Services) Regulations 1992 (SI 1992/662) ['the principal Regulations'].

These Regulations make changes to the way that pharmaceutical services are provided in localities that have been determined to be rural in character, that is, 'Controlled' for the purposes of the principal regulations.

They also make consequential amendments.

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 80, 83, 84, 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**

<u>Policy Background</u>
The current system which regulates the provision of pharmaceutical services within areas that have been determined to be rural in character in Wales has been problematic for general practitioners and community pharmacists who, in appropriate circumstances, may both dispense NHS prescriptions in rural locations. This is a result of acknowledged defects in the principal regulations which result in

applicants for inclusion in the pharmaceutical list of an LHB in respect of premises in rural locations being more favourably treated (they do not have to satisfy the "prejudice test" within the current regulations) depending upon whether they are already included in that list in respect of other premises within the LHB's area

Following discussion between Community Pharmacy Wales (CPW) and the Minister for Health and Social Services regarding the possibility of the amending of the regulatory framework which governs the provision of pharmaceutical services in Wales, it was agreed to establish a working group to look at the issues. A Control of Entry Working (COEW) Group was established and its first meeting was held on 29 September 2008. Stakeholders on the group included Welsh Assembly Government Health Department, CPW, General Practitioner Committee (GPC) Wales and the Business Services Centre (BSC).

The consensus of the COEW group was there was overwhelming support among stakeholders to implement changes to the current regime of consideration of applications for the provision of pharmaceutical services by pharmacists and doctors within rural localities under the NHS principal Regulations. The group considered that the changes made to such applications in England within the NHS (Pharmaceutical Services) Regulations 2005 should be implemented in Wales.

Responsibility for the provision of National Health Service pharmaceutical services is devolved to Wales and therefore these Regulations apply in relation to Wales. Similar arrangements apply in relation to England, Scotland and Northern Ireland in accordance with their respective regulations (although the exact arrangements depend upon the policy requirements for the relevant administration).

Objective

These Regulations seek to address anomalies and deficiencies in the making and consideration of applications by pharmacists and GPs for the provision of pharmaceutical services in rural areas.

The effect of this statutory instrument is to:

- require the registration of dispensing doctor practices;
- augment the class of person able to appeal a decision on the rurality of a location;
- introduce the concept of "reserved locations";

- make provision in relation to new applications to dispense by doctors;
- make provision in respect of additional premises and the relocation of dispensing practice premises;
- make provision for practice amalgamations;
- make transitional provisions.

6. **Implementation**

It is intended that these Regulations will come into force on 17 July 2009. If these Regulations were to be annulled then the failure to implement the changes which have been supported by CPW and GPC Wales to the way that pharmaceutical services may be provided in rural localities could destabilise the co-operation that currently exists between the GPC Wales and CPW, as the respective professional representative bodies for General Practitioners and Community Pharmacists in Wales.

These Regulations are intended to address current anomalies and to make changes which are intended to improve the delivery of pharmaceutical services within rural localities.

7. **Consultation**

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 does not resolve the identified anomalies within the principal Regulations nor does it implement the agreed proposals between the GPC and CPW and could therefore destabilise the goodwill and current co-operative relationship

between these two organisations and their respective members.

Option 2 – Regulatory change.
Make the amendments to the principal regulations contained within these Regulations.

This will resolve the identified anomalies, which it is hoped will improve relationships between GPs and community pharmacists in rural localities. It will also implement the agreed proposals between the GPC and CPW and will help to consolidate the current spirit of co-operation between these two organisations.

Option 3 – Voluntary Code
Draft a voluntary code of practice that general practitioners and community pharmacists could be asked to agree to adopt which may resolve the identified anomalies within the principal Regulations as they apply in relation to Wales. Such a code could have the same effect as that which the changes to the principal regulations will achieve.

To make and seek to implement such a code would require changes to the primary legislation which governs the provision of pharmaceutical services provided under the National Health Service as the terms of the National Health Service (Wales) Act 2006 (sections 80 and 83) require regulations to be made to govern the access to and the provision of pharmaceutical services under the National Health Service.

It is evident that the degree to which the identified anomalies and deficiencies would be resolved under this method would be dependant upon the extent to which the code of practice is taken up by individual contractors.

b) **Benefits**
There are likely to be a range of improved social and health benefits as a result of the implementation of this statutory instrument.

Option 1: No regulatory change.
Under this option the status quo continues so there are no additional benefits for the NHS contractors or patients. Indeed, it is likely that the failure to introduce the changes would result in a souring of the current spirit of co-operation between GPs and Community Pharmacists who practice in rural localities.

Option 2: Regulatory change.
Additional benefits for the NHS contractors and patients are likely to be achieved indirectly from the dispensing of NHS

prescriptions in the form of NHS contractor stability in rural areas.

Option 3: Voluntary code.
The realisation of benefits under this option would depend on the extent to which the code of practice was taken up by individual contractors. There would be a delay in the ability of Welsh Ministers to introduce such a code as changes to the primary legislation would be required.

c) **Costs**

Public sector organisations will be affected by the introduction of these Regulations; specifically LHBs and offices of the BSC (operated by Powys LHB) which process applications made under the principal Regulations. It is estimated that the changes will not result in the generation of a greater number of applications within any given period. The costs to LHBs and the BSC in relation to approving and inspection of General Practitioners premises is not directly quantifiable given that the method by which such inspections are undertaken is a matter for the LHBs and BSC.

All Community Health Councils (CHCs) will be affected as these Regulations provide that such bodies will have the right to make representations on an application and upon any subsequent appeal. It is estimated that this effect will be negligible as a CHC is not being required to make representations but may do should it so desire.

There are no foreseen additional costs to or effects on retail pharmacy businesses.

d) **Competition Assessment**

N/A

e) **Consultation**

Reason

All stake holders who participated in the COEW Group which undertook consideration of the issues surrounding the provision of pharmaceutical services in Wales were consulted on the draft of these Regulations.

The consultation was held in order to give the GPC and CPW the opportunity to confirm that the draft Regulations fully set out the changes in regard to the provision of pharmaceutical services in rural areas that were agreed in the negotiation between the GPC and PSNC at the national level. Also that the changes contained within the draft of these Regulations address and resolve the acknowledged anomalies within the principal Regulations in respect of applications in rural areas.

Period

The consultation ran from 20 March 2009 to 01 May 2009; a total of 42 days**.** A subsequent additional period of consultation was offered to the Board of Community Health Councils in Wales following the identification of Community Health Councils as affected public bodies; this additional period ran from 21 May 2009 to 4 June 2009.

Summary of Responses

Not all parties invited to comment on the consultation did so. In addition, two parties who were not invited submitted comments.

All parties responded in the positive, supporting the proposal to bring about those aspects of the principal regulations that relate to rural dispensing issues in Wales as those which were introduced in England 2005.

All parties acknowledged the importance of the provision of dispensing services by general practitioners in rural areas.

However, concerns have been raised by one respondent in regard to the practicality of the introduction of the concept of 'Reserved Locations' in prescribed circumstance set out in these Regulations. Having considered this response Officials of the Welsh Assembly Government Health and Social Services Department are satisfied that no changes are required to address the practicalities of the introduction of 'Reserved Locations'.

Subsequent Amendments

Following the responses to the consultation only minor typographical amendments were made and incorporated into the final draft of these Regulations.

f) **Post implementation review**

The effect of the changes made by these Regulations upon the processes for applications for the provision of pharmaceutical services within rural areas of Wales will be monitored by Officials of Welsh Assembly Government Department of Health and Social Services.

Likewise, officials will be monitoring the way in which stakeholders respond to the new Reserved Location status which is introduced by these Regulations.

g) **Summary**

The public sector [the LHB] will bear any costs which may arise as a result of the inspection and approval of the premises used by dispensing General Practitioners for the provision of services under the Regulations. Both GPC Wales and CPW will benefit from improved goodwill relations. The business sector and retail pharmacy companies will benefit from improvements to the application and appeal processes.