Explanatory Memorandum to the National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2010

This Explanatory Memorandum has been prepared by the Health and Social Services Directorate General and is laid before the National Assembly for Wales in accordance with Standing Order 24.1.

Description
These Regulations make changes to the National Health (Pharmaceutical Services) Regulations 1992. These will allow changes to legislation on the provision of stoma and urology appliances in Wales for both contractors and patients. These new arrangements form part of the changes required to maintain a joint Wales/England Drug tariff.

Matters of special interest to the Constitutional Affairs Committee
The equivalent legislation has already been made in England to come into effect on 1 April 2010. These Regulations are required to come into force with the minimum of delay and at the same time as England on 1 April 2010 and in order to comply with this restrictive deadline it is considered necessary to breach the convention that they should be laid before the Assembly for 21 calendar days before coming into force. The Minister for Business and Budget has written to the Presiding Officer notifying him of reasons pertinent to the breach.

Legislative Background
The National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2010 are made by the Welsh Ministers using the powers contained in sections 80, 83, 86, 121, 203(9) of the National Health Service (Wales) Act 2006. Powers and functions of the National Assembly for Wales have transferred to Welsh Ministers in accordance with section 4 of and Schedule 2, Part 1, paragraph 1 of the National Health Service (Consequential Provisions) Act 2006 and paragraph 30 of Schedule 11 to the Government of Wales Act 2006.
The Regulations follow the negative resolution procedure.

Purpose and intended effect of the legislation
The National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2010 amend the National Health (Pharmaceutical Services) Regulations 1992 to improve patient care and ensure equity to dispensing appliance contractors and pharmacy contractors for the provision of equivalent services. These particular changes will -

- define and standardise the services that both dispensing appliance contractors (DACs) and pharmacy contractors provide in the normal course of their business to include services such as a repeat

prescription service, appropriate advice and a home delivery service;

- make provision for Advanced services, which DACs and pharmacy contractors may choose to provide, to include stoma appliance customisation and appliance use reviews; and

- require appliance contractors to operate within a similar clinical governance framework to pharmacy contractors.

Implementation
Failure to implement this legislation would undermine continuing parity between Wales/England pharmaceutical services and prejudice the joint Wales/England Drug Tariff.

Consultation

Details of the consultation undertaken are included in the Regulatory Impact Assessment below.

Regulatory Impact Assessment

Option 1 – No regulatory change

Make no amendments to the principle regulations.

This would result in different terms and levels of service for contractors and patients in Wales and England. It would undermine the core principles of the jointly negotiated and administered pharmacy contract and prejudice the joint Wales/England Drug Tariff which is key to maintaining parity in pharmaceutical services.

Option 2 –Regulatory change

Make the amendments to the principle regulations that are contained within these amendments.

This will avoid the anomalies identified in option 1.

Option 3 – Take a different policy direction

Stakeholders have agreed that the amendments to the principle regulations offer a pragmatic approach to improving terms of service for contractors and care for patients. Adopting a different approach would be counterproductive and unacceptable within the current structure of the pharmacy contract and Drug Tariff.

Benefits

There will be improved terms of service for contractors and social and health benefits for patients as a result of implementing this legislation.

Option 1 – No regulatory change

Patients in Wales would not have access to certain services offered to similar individuals in England which may result in social/economic/health problems.

Option 2 – Regulatory change

Benefits to contractors and patients will be achieved directly

Option 3 – Take a different policy direction

Consultation with stakeholders has identified option 2 as the most efficient method of improving pharmaceutical services in this area taking a different policy approach would compromise this.

Costs

There are no additional costs associated with this legislation for 2010/11. There is recognition that as some new services will be demand led costs may rise as these services become more widespread and, if demand exceeds budget then saving will need to meet by finding savings elsewhere in the MEG.

Consultation

All relevant parties including contractors, Local Health Boards, Health Solutions Wales and the Business Services Authority have been consulted on proposals with the intent to make these Amendments and have seen and been given the opportunity to comment on the draft Instrument. Major Stakeholders have been supportive of the proposals. Some questions were raised necessitating minor amendments to the legislation and regarding guidance for some services which officials will prepare during the transition period.

Post Implementation Review

The effect of the changes made by this legislation will be monitored by Officials, Business Services Centres and clinical governance mechanisms within LHBs.

Summary

The regulatory option embedded in this Instrument provides the most practical option for administering this legislation.