Explanatory Memorandum to the National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2011

This Explanatory Memorandum has been prepared by the Welsh Government's Department for Health, Social Services and Children and is laid before the National Assembly for Wales in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1.

Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of the National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2011. I am satisfied that the benefits outweigh any costs.

Lesley Griffiths AM
Minister for Health and Social Services, one of the Welsh Ministers

4 December 2011

1. Description

These Regulations amend the National Health (Pharmaceutical Services) Regulations 1992 ("the principal Regulations") in respect of the NHS terms of services for pharmacists – "pharmacists" in this context being a term which includes partnerships of pharmacists and pharmacy businesses, not just individual pharmacists. Pharmacists providing NHS pharmaceutical services are included in a pharmaceutical list of a Local Health Board, and their NHS terms of services are the terms on which they are included in that list.

2. Matters of special interest to the Constitutional and Legislative Affairs Committee

There are no matters of special interest to note.

3. Legislative Background

The National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2011 ("the Regulations") are made by the Welsh Ministers using the powers contained in sections 80, 83 and 203 of the National Health Service (Wales) Act 2006. The Regulations follow the negative resolution procedure.

4. Purpose and intended effect of the legislation

The Regulations amend the provisions of the NHS terms of service for pharmacists that relate to participation in an acceptable system of clinical governance. These obligations will improve the safety and quality of NHS pharmaceutical services by ensuring that procedures, which are currently required only as part of good professional practice, become requirements of the NHS terms of service. Similar amendments have been made to the regulations governing NHS pharmaceutical services in England. Failure to implement this legislation would undermine continuing parity between pharmaceutical services in England and Wales. The provisions are modified so as to:

- Require that there is a clinical governance lead person for each pharmacy, appointed as such by the pharmacist (or that is the pharmacist), who is knowledgeable about both the pharmacy procedures of that pharmacy and the other NHS services that are available in the locality of that pharmacy;
- Require that pharmacists reflect on the results of their annual patient satisfaction survey, take appropriate action and publish the results;
- Require that all patient safety incidents be reported to the National Patient Safety Agency and that all pharmacies maintain a patient safety incident and near-miss log;
- Require that pharmacies have procedures which protect staff who provide information in good faith and not for purposes of personal gain to the General Pharmaceutical Council or to a Local Health Board which includes an allegation of a serious nature which they reasonably believe to be substantially true;
- Require that patient safety notices are acted upon within required timescales. And that actions taken in response to the alerts are recorded;
- Require that where pharmacists publicise NHS services that are available at or from the pharmacy there should be an acknowledgement that these are funded by the NHS;
- Require that pharmacies participate in information governance and clinical governance programmes;
- Require that pharmacists have in place proportionate cleanliness and infection control measures;

- Require that there will be a clear separation between the healthcare environment (where patients will receive NHS services) and the non-professional area of the pharmacy.

Regulation 3 of the Regulations is a transitional provision which essentially allows pharmacists who are on pharmaceutical lists when the Regulations come into force until 31 March 2012 to adapt their systems of clinical governance to accommodate their new and modified obligations, provided they are complying, in the case of modified obligations, with the version of the obligation that existed prior to these Regulations coming into force.

5. Consultation

Community Pharmacy Wales, as the body recognised as being representative of community pharmacy contractors in Wales, and Local Health Boards have been extensively consulted on these changes.

Regulatory Impact Assessment

Options

Option 1 – No regulatory change

Make no amendments to the principal 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.

Option 2 –Regulatory change

Make the amendments to the principal Regulations that are contained within the Regulations.

This will avoid the anomalies identified in option 1.

Option 3 – Take a different policy direction

Stakeholders have agreed that the amendments to the principal Regulations will both improve the terms of service for contractors and the care for patients. Adopting a different approach would not retain the accepted parity between pharmaceutical services in Wales and England and would be counterproductive.

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

Individuals accessing pharmaceutical service in Wales would not be afforded the same level of service as in England. The changes improve quality and safety and not making the change could result in services in Wales being of lesser quality than those in England; this would undermine the potential contribution of pharmacy to improving health.

Option 2 – Regulatory change

Benefits to patients will be achieved directly

Option 3 – Take a different policy direction

Consultation has identified option 2 as the most efficient method of improving the quality and safety of pharmaceutical services, taking a different policy approach would compromise this.

Costs

There are no additional costs associated with this legislation. All changes are to be delivered within the existing contractual funding for pharmacists. These changes form part of a wider agreement regarding changes to existing, and new directed services which improve patient care.

Consultation

Community Pharmacy Wales and Local Health Boards have been consulted on the proposals with the intent to make the amendments that are contained in the Regulations and have seen and been given the opportunity to comment on the draft Instrument. 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 transitional period.

Competition Assessment

The competition filter has been completed and indicates that the regulation is unlikely to have a significant detrimental effect on competition. The amendments proposed incorporate matters considered to be good professional practice in NHS terms of service for pharmacists therefore, the new amendments do not make any significant contribution to regulatory burden in the pharmacy market. Therefore, no competition issues are considered to arise.

Post Implementation Review

The effect of the changes made by this legislation will be monitored by officials and by Local Health Boards (within their remit to oversee the provision of NHS pharmaceutical services).

Summary

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