

Explanatory Memorandum to National Health Service (Therapeutic Radiographer Independent Prescriber and Dietitian Supplementary Prescriber) (Miscellaneous Amendments) (Wales) Regulations 2016.

This Explanatory Memorandum has been prepared by Health and Social Services Group and is laid before the National Assembly for Wales in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1

Cabinet Secretary's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of National Health Service (Therapeutic Radiographer Independent Prescriber and Dietitian Supplementary Prescriber) (Miscellaneous Amendments) (Wales) Regulations 2016.

Vaughan Gething AM
Cabinet Secretary for Health, Well-being and Sport.

19 December 2016

1. Description

The National Health Service (Therapeutic Radiographer Independent Prescriber and Dietitian Supplementary Prescriber) (Miscellaneous Amendments) (Wales) Regulations 2016 (“the Regulations”) enable registered therapeutic radiographers to become independent prescribers and registered dietitians to become supplementary prescribers by amending the:

- National Health Service (Pharmaceutical Services) (Wales) Regulations 2013 (S.I.2013/898 (W.102));
- National Health Service (General Medical Services Contracts) (Wales) Regulations 2004 (S.I. 2004 478(W.48));
- National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007 (S.I. 2007 121(W.11)); and
- Single Use Carrier Bags Charge (Wales) Regulations 2010 (S.I. 2010/2880 (W. 238).

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

There are no matters of special interest to the Constitutional and Legislative Affairs Committee.

3. Legislative background

UK wide medicines legislation permits supplementary and independent prescribing in the UK: The Human Medicines Regulations 2012 set out who is an appropriate practitioner in relation to any prescription only medicine (POM) and were amended on 1st April 2016 by the Human Medicines (Amendment) Regulations 2016 (SI 2016//186) to include therapeutic radiographer independent prescribers and registered dietitian supplementary prescribers as appropriate practitioners for providing a prescription. It is a matter for each devolved administration to decide whether and how this extension of professionals who are entitled to prescribe is implemented in each of their countries.

Sections 47, 80, 83 , and 203(9) and (10) of the National Health Service (Wales) Act 2006 (“the 2006 Act”) give the Welsh Ministers the power to make regulations which extend prescribing rights to therapeutic radiographer independent prescribers and dietitian supplementary prescribers.

Amendment to the Single Use Carrier Bags Charge (Wales) Regulations 2010 (SI 2010/2880 (W.38)) will provide that carrier bags used solely to contain medicinal products or listed appliances provided in accordance with a prescription issued by a therapeutic radiographer independent prescriber are exempt from charge. The Single Use Carrier Bags Charge (Wales) Regulations 2010 do not require amendment to exempt from charging carrier bags used to dispense prescriptions of registered dietitians as they already exempt from charging bags used to dispense prescriptions of supplementary prescribers as defined in the Human Medicines

Regulations 2012. This definition of supplementary prescriber includes registered dietitians.

Sections 77 and 90 of, and paragraph 3 of Schedule 6 to, the Climate Change Act 2008 give the Welsh Ministers the power to make regulations to extend the exemption from the requirement to charge for single use carrier bags.

The Regulations are subject to the negative resolution procedure.

4. Purpose & intended effect of the legislation

Policy Background

The extension of prescribing responsibilities to non medical professions was introduced in Wales to support implementation of 'Designed for Life – Creating World Class Health and Social Care for Wales in the 21st Century, May 2005'. Extending prescribing rights to therapeutic radiographers and registered dietitians will continue to support the modernisation agenda and is consistent with Welsh Government's well-being objectives set by the Welsh Government under the Well-being of Future Generations (Wales) Act 2015, particularly the objective of developing a healthier Wales.

Introducing non – medical prescribing in Wales has enabled the following:

- Increased patient choice in accessing medicines;
- Improved access to advice & services;
- Appropriate use of a skilled healthcare workforce;
- Contribution to the introduction of more flexible team working across the NHS;
- Increased capacity to meet demand of new ways of working, and
- Improvement in patient care without compromising patient safety.

Non medical prescribing has developed since its introduction in Wales to include two broad groups of non medical prescribing: Supplementary Prescribing and Independent Prescribing.

Purpose and Effect

The Regulations will extend independent prescribing to therapeutic radiographers and supplementary prescribing to registered dietitians in Wales who are suitably qualified to do so. These Regulations will amend the:

- (i) National Health Service (Pharmaceutical Services) (Wales) Regulations 2013 (S.I.2013/898 (W.102)),
- (ii) National Health Service (General Medical Services Contracts) (Wales) Regulations 2004 (S.I. 2004/478 (W.48)), and

(iii) National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007 (S.I. 2007/121(W. 11));

by defining “therapeutic radiographer independent prescriber” and adding them to the definition of “prescriber” and adding dietitian to the definition of supplementary prescriber. This then enables these two prescriber groups to prescribe medicines in Wales.

It is intended that the expansion of prescribing rights to these two groups of healthcare professional will contribute to:

- greater patient choice in accessing medicines;
- appropriate use of a skilled healthcare workforce;
- more flexible team working across the NHS;
- increased capacity to meet increasing demand on current independent prescribers, for example, doctors and prescribing nurses;
- improvement in patient care without compromising patient safety;
- enable the development of new roles and new ways of working which will better utilise the skills of registered dietitians.

The amendment to the Single Use Carrier Bags Charge (Wales) Regulations 2010 will extend the exemption from the requirement to charge for single use carrier bags. Currently, carrier bags used solely to contain medicinal products or listed appliances provided in accordance with a prescription issued by specific prescribers are exempt from charge. The amendment to the Regulations will extend this exemption so that carrier bags used solely to contain medicinal products or listed appliances provided in accordance with a prescription issued by therapeutic radiographer independent prescribers will also be exempt from charge¹.

Implementation

It is intended that the National Health Service (Therapeutic Radiographer Independent Prescriber and Dietitian Supplementary Prescriber) (Miscellaneous Amendments) (Wales) Regulations 2016 will come into force on 9 January 2017.

If these Regulations were to be annulled then there would be no extension in Wales of independent prescribing to therapeutic radiographers or supplementary prescribing to registered dietitians and no exemption from a charge for single use carrier bags provided by pharmacies where medicines are prescribed by these two types of prescriber.

¹ As set out at Part 3 above, bags used to dispense prescriptions of registered dietitians are already covered by the exemption as bags used to dispense prescriptions of supplementary prescribers are exempt from charge. The existing definition of supplementary prescriber in the Single Use Carrier Bags Charge (Wales) Regulations 2010 extends to registered Dietitians.

5. Consultation

An Allied Health Professionals Prescribing and Medicines Supply Mechanisms Scoping Project was undertaken by the Medicines and Healthcare products Regulatory Agency (MHRA) and Department of Health (England) in 2009 to evaluate extending prescribing to a number of allied health professionals.

NHS England consulted on proposals to enable registered therapeutic radiographers to become independent prescribers between 26 February and 22 May 2015 and between 26 February and 26 April 2015 for registered dietitians to become supplementary prescribers. Responses to the consultation were received from all four UK countries and from a wide range of respondents including patients and the general public, Royal Colleges, professional bodies, provider organisations, clinicians and education providers. The majority of responses including respondents from Wales, supported independent prescribing by the two new categories of prescriber. The Commission on Human Medicines recommended amending legislation to allow independent prescribing by registered therapeutic radiographers and supplementary prescribing by registered dietitians.

There has been no consultation on the Regulations with stakeholders because the Regulations make technical changes to the:

- (i) National Health Service (Pharmaceutical Services) (Wales) Regulations 2013 (S.I.2013/898 (W.102)),
- (ii) National Health Service (General Medical Services Contracts) (Wales) Regulations 2004 (S.I. 2004/478 (W.48)),
- (iii) National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007 (S.I. 2007/121(W. 11)).

to implement the Human Medicines (Amendment) Regulations 2016 which extended the right to therapeutic radiographers to become independent prescribers and to registered dietitians to become supplementary prescribers. As set out above, the extension of prescribing rights contained in the Human Medicines (Amendment) Regulations 2016 was subject to a full UK wide public consultation before the Amendment Regulations were made. The amendment to the Single Use Carrier Bags Charge (Wales) Regulations 2010 is a minor technical amendment to update the list of prescribers whose prescriptions may be bagged without attracting the single use carrier bag charge.

6. Regulatory Impact Assessment (RIA)

These Regulations have no impact on the statutory duties of the Welsh Government: to provide equality of opportunity for all people, maintain a Welsh language strategy, maintain a sustainable development scheme (sections 77 – 79 Government of Wales Act 2006). They also do not impose any additional burdens upon the statutory partners: the partnership council, local government, the voluntary sector, and business sector (sections 73 – 75 of that Act).

A Regulatory Impact Assessment has not been prepared for these Regulations because they have no impact on local government, business, charities or voluntary bodies.