

Explanatory Memorandum to The National Health Service (Paramedic Independent Prescriber and Paramedic Supplementary Prescriber) (Wales) (Miscellaneous Amendments) Regulations 2019

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

Minister for Health and Social Services' Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of The National Health Service (Paramedic Independent Prescriber and Paramedic Supplementary Prescriber) (Wales) (Miscellaneous Amendments) Regulations 2019.

Vaughan Gething AM
Minister for Health and Social Services
31 January 2019

1. Description

The National Health Service (Paramedic Independent Prescriber and Paramedic Supplementary Prescriber) (Wales) (Miscellaneous Amendments) Regulations 2019 (“the Regulations”) make amendments to the following sets of Regulations:

- The National Health Service (General Medical Services Contracts) (Wales) Regulations 2004;
- The National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007; and
- The National Health Service (Pharmaceutical Services) (Wales) Regulations 2013

by extending the definition of prescriber to include paramedic independent prescribers. They also amend the definition of supplementary prescriber in those Regulations to include paramedic supplementary prescribers. The changes are required as a result of the addition of paramedics to the category of independent prescriber and supplementary prescriber under amendments made to the Human Medicines Regulations 2012 by the Human Medicines (Amendment) Regulations 2018.

The Regulations also amend the Single Use Carrier Bags Charge (Wales) Regulations 2010 by extending the exemption from the requirement to charge for single use carrier bags to include products prescribed by a paramedic independent prescriber and a paramedic supplementary prescriber.

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 2018 by the Human Medicines (Amendment) Regulations 2018 (SI 2018 no. 199) to include paramedic independent prescribers and paramedic 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.

The power to amend the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004, the National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007 and the National Health Service (Pharmaceutical Services) (Wales) Regulations 2013 to extend the definitions of an independent prescriber and supplementary prescriber to include paramedics are contained in sections 47, 80, 83, 121 and 203(9) and (10) of the National Health Service (Wales) Act 2006 (“the 2006 Act”).

Amendments 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 paramedic independent and supplementary prescriber are exempt from charge.

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'.

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.

Extending prescribing rights to registered paramedics 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.

Prosperity for All: The National Strategy aims to increase access to health services and "take significant steps to shift our approach for treatment closer to home". By allowing paramedics to prescribe medicines within their competence, this will allow prescribing to be undertaken at the point of treatment and not require the patient to be seen by a doctor and will avoid admissions to hospital. It will also support the prudent health agenda and our long term plan a 'Healthier Wales' our Plan for Health and Social Care by delivering care as close to home as possible and reducing reliance on hospitals.

Purpose and Effect

The Regulations will extend independent prescribing and supplementary prescribing to registered paramedics 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 adding paramedics to the definition of “independent prescriber” and “supplementary prescriber”. This then enables paramedics to prescribe medicines in Wales as both independent and supplementary prescribers.

It is intended that the expansion of prescribing rights to this group of healthcare professionals will contribute to:

- improving patients care, experience and safety;
- providing more timely access to appropriate treatment;
- providing care closer to home and support patients to self-manage a condition within their home;
- providing greater patient choice in accessing medicines;
- providing appropriate use of a skilled healthcare workforce;
- more flexible team working across the NHS;
- avoiding unnecessary trips to hospitals or additional appointments with other health professionals such as GPs and prescribing nurses to access the treatment and medicines they need;
- enabling the development of new roles and new ways of working which will better utilise the skills of registered paramedics.

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 paramedic independent prescribers and paramedic supplementary prescribers will also be exempt from charge.

Implementation

It is intended that The National Health Service (Paramedic Independent Prescriber and Paramedic Supplementary Prescriber) (Wales) (Miscellaneous Amendments) Regulations 2019 will come into force on 20 February 2019.

If the Regulations were to be annulled then there would be no extension in Wales of independent prescribing and supplementary prescribing to paramedics and no resulting exemption from a charge for single use carrier bags used solely to contain medical products or listed appliances prescribed by this type of prescriber.

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. A project board was set up and through a phased approach recommended extending prescribing rights to a number of allied health professionals.

In 2015 it was proposed that legislation be amended to allow paramedics, working at advanced level, to be able to prescribe. NHS England carried out a 12-week consultation from 26 February 2015 to 22 May 2015 to discuss a number of options. Responses to the consultation were received from all four UK countries and from a wide range of respondents including patients and the general public, professional bodies, provider organisations, clinicians and education providers. The consultation received a total of 536 responses from across the UK. 21 (4%) responses were received from Wales. In total, 96% of organisations and 90% of individuals were in favour of advanced paramedics being able to prescribe.

There has been no consultation on these 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)); and
- (iii) National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007 (S.I. 2007/121(W. 11)),

to implement changes which have been made to the Human Medicines Regulations 2012 by the Human Medicines (Amendment) Regulations 2018 which extended the right to paramedics to become independent prescribers and supplementary prescribers. As set out above, the extension of prescribing rights contained in the Human Medicines (Amendment) Regulations 2018 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 72 – 75 of that Act).

A Regulatory Impact Assessment has not been prepared for these Regulations because they have no impact on public or private sectors, charities or voluntary bodies.