Explanatory Memorandum to The National Health Service (Primary Medical Services and Primary Dental Services)(Wales)(Amendment and Transitional Provision) Regulations 2016

This Explanatory Memorandum has been prepared by the 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's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of The National Health Service (Primary Medical Services and Primary Dental Services)(Wales)(Amendment and Transitional Provision) Regulations 2016.

Mark Drakeford AM Minister for Health and Social Services 29 January 2016

1. Description

These Regulations make a number of miscellaneous amendments to the -

- National Health Service (General Medical Service Contracts) (Wales) Regulations 2004 (S.I. 2004/478, as amended), ("the GMS Contracts Regulations");
- the National Health Service (General Medical Service Contracts) (Prescription of Drugs etc) (Wales) Regulations 2004 (S.I. 2004/1002, as amended), ("the GMS Prescription of Drugs Regulations");
- the National Health Service (General Dental Services Contracts) (Wales) Regulations 2006 (S.I. 2006/490, as amended), ("the GDS Regulations"); and
- the National Health Service (Personal Dental Services Agreements) (Wales) Regulations 2006 (S.I. 2006/489, as amended), ("the PDS Regulations").

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

None.

3. Legislative background

The Regulations will be made pursuant to powers under sections 46(2), 47, 61, 66, 203(9) and (10) of the National Health Service (Wales) Act 2006.

These Regulations will follow the negative resolution procedure. They will come into force on 1 March 2016.

4. Purpose & intended effect of the legislation

<u>The National Health Service (General Medical Services Contracts) (Wales)</u> <u>Regulations 2004 S.I 2004/478, as amended (W.48) ("the GMS Regulations")</u>

Provision of General Medical Services (GMS) to certain armed forces personnel

Currently health care for armed forces personnel is provided by the Defence Medical Services (DMS). The GMS Regulations currently requires that patients who join HM Forces are removed from the list of GPs providing GMS.

There are a certain set of circumstances where the MoD consider registration with an NHS GP and provision of care from a patient's home address is more suitable than primary care provision to be delivered through DMS. The GMS regulations, however, do not allow dual registration but the patients will often require care for longer than the 3 month limit allowable under temporary resident arrangements.

The amending Regulations allow a GMS contractor to accept a member of Her Majesty's armed forces as a patient for a maximum period of two years, if that person has been authorised in writing by DMS to receive medical services under the contract at the contractor's practice and the contractor is satisfied that the person is living or working within the contractor's practice area.

The DMS will retain responsibility for meeting occupational health needs, but the individual's primary care needs would be delivered through registration for NHS primary medical care services with a GP practice.

Correct terminology for the Armed Forces

The definition for Armed Forces has been revised to "armed forces of the Crown". The amending Regulations amends the definition and any references to Armed Forces in the GMS Regulations.

<u>The National Health Service (General Medical Services Contracts) (Prescription</u> of Drugs Etc.)(Wales) Regulations 2004 ("the 2004 Regulations")

GPs in Wales may only prescribe antivirals when either: the Welsh Ministers have notified them, based on the incidence of confirmed cases of influenza, that influenza is circulating within the community; or where local virological surveillance indicates that influenza is circulating in the locality in which the patient(s) reside. There are further restrictions on GPs which limit prescribing to adults and children over one year who are in specified at-risk groups.

Earlier in 2015 the marketing authorisation of oseltamivir was amended to allow it to be prescribed to infants under one year of age. The marketing authorisation change now creates a situation in which a GP would not be able to prescribe oseltamivir for prophylaxis or treatment of an infant under one year of age despite it being shown to be a safe and effective intervention. Instead it would be necessary for oseltamivir to be prescribed by a hospital doctor. Given that oseltamivir has been shown to be safe and effective, as demonstrated by the extension to its marketing authorisation, the current restriction on GP prescribing to infants in this group is no longer warranted.

In addition to the changes to oseltamivir, there was an opportunity to make a small number of changes to reflect the current availability of medicines for the treatment of erectile dysfunction (ED). These medicines are currently restricted on NHS prescription and are only available in certain circumstances. In June 2015, the All Wales Medicines Strategy group recommended that avanafil, a new ED treatment be made available in Wales. The prescribing of avanafil is not currently restricted in the same way as prescribing of other ED treatments. The amending Regulations will allow avanafil to be added to the list of restricted treatments and apomorphine, thymoxamine and moxisylyte removed from the list because they are no longer in common use in the UK.

<u>The National Health Service (General Dental Services Contracts)(Wales)</u> <u>Regulations 2006 (''the GDS Regulations'') and</u>

<u>The National Health Service (Personal Dental Services Agreements)(Wales)</u> <u>Regulations 2006 ("the PDS Regulations")</u>

Telephone services

Patients at practices who use non-geographical telephone numbers are being disadvantaged as they pay a higher standard rate for their calls.

The amending Regulations will disallow General Dental Practitioners who contract with a local health board in Wales to use non-geographical telephone numbers when providing NHS dental services.

Termination of a dental contract on the death of an individual dental Practitioner

The GDS Regulation and the PDS Regulations do no allow sufficient time for the estate of the deceased contract holder to fully consider the operational issues of the contract during a very difficult time. The amending Regulations will extend the timescales which the estate of a contract holder has to confirm to the health board that they wish to continue to hold the contract. The time period the estate then has to arrange the continuation of services is also extended.

Amendments to the GMS, GDS and PDS Regulations

Providers of NHS primary medical services and primary dental services may choose their contract with Local Health Boards to be either an NHS contract or a non-NHS contract. Disputes arising from NHS contracts are determined by the Welsh Ministers. Disputes arising from non-NHS contracts are determined through the Courts unless the contractor opts to use and be bound by the NHS disputes procedure.

Contractors may alter the status of their contract if they wish. Currently, if the holder of an NHS contract changes the status of the contract to a non-NHS contract any disputes, relating to the period when the contract was an NHS contract may, in the view of the Court, not be determined by the Welsh Ministers.

This represents a financial risk to health boards if a contractor is able to change their status to avoid the recovery of monies by a health board through the contract dispute resolution procedure for the under delivery of an agreed level of contracted medical or dental service provision. The amending Regulations will provide for disputes arising from contracts deemed NHS general medical services contracts, general dental services contracts and personal dental services agreements to be heard by the Welsh Ministers despite the contractor subsequently changing the status of the contract from an NHS contract to a non-NHS contract.

5. Consultation

Discussions were held with the General Practitioners Committee Wales, Community Pharmacy Wales, British Dental Association (Wales), Welsh General Dental Practitioner Committee and LHB Representatives. The amendments regarding Army Personnel were discussed with the DMS. A further 2 week informal consultation exercise was undertaken with the relevant stakeholders.

All organisations are content with the proposed amendments. The British Dental Association (Wales) did, however wish for a longer period of time to be permitted and greater flexibility to transfer the contract to a dentist identified by the deceased contractor's personal representatives. Their comments have been noted. While expressing this view, the BDA also thought it sensible to reflect the position in England. The amending Regulations reflect the position in England.

6. Regulatory Impact Assessment (RIA)

A Regulatory Impact Assessment has not been prepared for this instrument as it imposes no costs or no savings, or negligible costs or savings on the public, private or charities and voluntary sectors.

This legislation has no impact on the statutory duties (sections 77-79 of the Government of Wales Act 2006) or statutory partners (sections 72-75 of that Act).