

EXPLANATORY MEMORANDUM TO
THE NATIONAL HEALTH SERVICE
(PRIMARY MEDICAL SERVICES AND PHARMACEUTICAL SERVICES)
(MISCELLANEOUS AMENDMENTS) REGULATIONS 2006

2006 No. 1501

1. This explanatory memorandum has been prepared by Department of Health and is laid before Parliament by Command of Her Majesty.

2. Description

2.1 These Regulations amend the:-

- i. National Health Service (General Medical Services Contracts) Regulations 2004 (SI 2004/291) - which set out the framework for General Medical Services (GMS) contracts;
- ii. National Health Service (Personal Medical Services Agreements) Regulations 2004 (SI 2004/627) - which set out the framework for Personal Medical Services (PMS) agreements;
- iii. National Health Service (Pharmaceutical Services) Regulations 2005 (SI 2005/641) – which govern the provision of pharmaceutical services under Part 2 of the National Health Service Act 1977.

The amendments update the various Regulations to reflect policy developments and associated legislative changes introduced since the original Regulations were made, or last amended.

3. Matters of special interest to the Joint Committee on Statutory Instruments.

3.1 None

4. Legislative Background

4.1 These Regulations amend a number of Statutory Instruments, as detailed above, that control the way in which primary medical services are delivered pursuant to the provisions contained in Part 1 of the National Health Services Act 1977.

4.2 The changes being introduced through this instrument can be grouped under the following headings:-

- i. changes to reflect revised and new categories of independent prescribers;
- ii. changes to reflect new training arrangements for medical practitioners;
- iii. minor changes to the Pharmaceutical Regulations.

4.3 The first category of amendments arise as a result of new arrangements for the independent prescribing of drugs and appliances by nurses and pharmacists. Independent nurse prescribers, unless they are community practitioner nurse

prescribers, will no longer be limited to prescribing from a particular formulary; neither will the new category of independent prescriber known as pharmacist independent prescribers. These amendments take account of the revised and new categories of prescriber and of the terminology to be used for annotations in the register maintained by the Nursing and Midwifery Council..

4.4 The second category of amendments reflect proposed amendments to the National Health Services (Performers List) Regulations 2004 (SI 2004/585) that will provide that doctors undertaking supervised postgraduate education training will not need to be included in a Primary Care Trust's Performers' List. These Regulations reflect those proposed changes and provide that a doctor undergoing such training may, subject to certain conditions, provide medical services under GMS Contracts and PMS Agreements without the need to be included in a Performers List or to provide clinical references.

4.5 The third category of amendments are minor changes to the National Health Service (Pharmaceutical Services) Regulations 2005 ("the Pharmaceutical Services Regulations"). Firstly, they amend the definition of a PMS contractor to reflect the fact that a PCT can be both a commissioner and a provider of services. Secondly, they change paragraph 8(2) of Schedule 2 (Terms of Service of Dispensing Doctors) to the Pharmaceutical Services Regulations. Paragraph 8(2) links the payment to be made to dispensing doctors who are providing their services by virtue of consent under Part 5 of the Pharmaceutical Services Regulations to the payments to be made to GMS Contractors pursuant to directions (the Statement of Financial Entitlements) made under section 28T of the National Health Service Act 1977. At present, the link relates to the provision of drugs and appliances. A new "Dispensing Quality Payment" is to be introduced for GMS Contractors which will relate to the provision of additional services associated with the dispensing process. The amendment to paragraph 8(2) of the Pharmaceutical Services Regulations provides that the link to the Statement of Financial Entitlements extends to any additional services associated with the dispensing process that may be provided by a dispensing doctor.

5. **Extent**

5.1 This instrument applies to England only.

6. **European Convention on Human Rights**

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. **Policy background**

Independent Prescribing

7.1 The changes relating to prescribing form part of the Government's policy of modernising the NHS. They enable appropriately trained healthcare professionals to prescribe medicines in the interests of improving patient care by appropriate use of professional skills.

- 7.2 The amendments to expand nurse prescribing and to introduce independent prescribing by pharmacists were subject to public consultation and advice to Ministers by the then Committee on Safety of Medicines. Detailed analyses of the outcome of the two public consultation exercises have been published on the MHRA website: www.mhra.gov.uk. In both cases, there was general support for the proposals although doctors' organisations were more reticent, suggesting much more limited change.
- 7.3 "Improving Patients' Access to Medicines: A Guide to Implementing Nurse and Pharmacist Independent Prescribing with the NHS in England" was produced in April 2006. Its aim is to help promote safe and effective prescribing by Nurse and Pharmacist Independent Prescribers and to assist implementation in the NHS. It is applicable to both the NHS and the independent sector and provides information and advice on good practice for Nurse and Pharmacist Independent Prescribers.

Amendment to Performers List Regulations

- 7.4 A Modernising Medical Careers (MMC) project is reforming postgraduate medical education. One of the key changes is that from August 2005, a two year Foundation Programme has replaced the existing Pre-Registration House Officer (PRHO) year and the first year of Senior House Officer training. As part of the second year of foundation training around 55% of 2006/07 trainees will undertake a placement in general practice, rising to 80% in subsequent years. This will involve around 6,000 doctors undertaking placements in primary care lasting around four months.
- 7.5 Doctors performing primary medical services are normally required to be on a PCT Performer's List to ensure patient safety. The Performers List Regulations require that doctors provide a range of information about themselves and they are also required to provide an enhanced criminal record certificate. Ministers have given permission for the year two foundation trainees to be exempt from the requirement to be on a performers list for the duration of their primary care placement.
- 7.6 Checks usually carried out prior to being included in a Performers List will be undertaken by the postgraduate deanery, who will certify to the PCT and the training practice that the checks have been carried out. It was agreed therefore, that there was no point in PCTs repeating these checks as it would be disproportionately burdensome and would provide no extra patient safety benefit.
- 7.7 MMC has consulted their network of post-graduate deans on the implications of this change. DH policy officials have consulted the relevant committees of the BMA who support this change.
- 7.8 The proposed changes to GMS and PMS Regulations will allow contractors to employ or engage doctors undergoing a programme of post-registration, supervised clinical practice, approved by the Postgraduate Medical and Education Training Board, to perform primary medical services in that area of that Trust, but only in so far as the performance of those services constitutes part of that programme.

- 7.9 In 2004, advice was issued by the Department of Health to the NHS on list management issues. It is intended to update that advice later this year. The revision will take account of the amendment in these Regulations together with other changes it is proposed to make following two recent Judicial Reviews into how PCTs manage their performers list processes.
- 7.10 In addition to the subject specific consultation outlined above the Department has consulted NHS Employers, the General Practitioners Committee of the British Medical Association and the Pharmaceutical Services Negotiating Committee on the content of these Regulations. They have signified that they are content for these changes to be brought forward
- 7.11 The Devolved Administrations have also been made aware of the content of the Regulations.
- 7.12 The GMS Regulations run to some 90 pages and the PMS Regulations to 79. Both sets of Regulations require regular updating, this being the fifth such amendment since their introduction in April 2004. The Department keep the need for consolidation in mind whenever such amendments are introduced. However, in balancing the extent of the changes made against the costs of consolidation (such as the need for Ministers to address every aspect of a consolidated Instrument, the public and NHS expense and inconvenience in having to buy and consider new legislation when they have got used to the existing legislation, the resource implications for both the Department and professional bodies such as the GPC in consulting on the consolidated document etc.) the Department does not judge that consolidation would be beneficial at this stage.

8. Impact

- 8.1 A Regulatory Impact Assessment has not been prepared for this instrument, as it has no new impact on business, charities or voluntary bodies.

9. Contact

Steve Rowlands at the Department of Health Tel: 0113-2545192 (or Email – steve.rowlands@dh.gsi.gov.uk) can answer any queries regarding the instrument.