

**EXPLANATORY MEMORANDUM TO THE
NATIONAL HEALTH SERVICE (PRIMARY MEDICAL SERVICES)
(MISCELLANEOUS AMENDMENT) REGULATIONS 2005**

2005 No.893

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

2. Description

2.1 These Regulations make a number of amendments to the:-

- i. National Health Service (General Medical Services Contracts) Regulations 2004 (SI 2004/291);
- ii. National Health Service (Personal Medical Services Agreements) Regulations 2004 (SI 2004/627); and
- iii. National Health Service (Performers Lists) Regulations 2004 (SI 2004/585).

The amendments seek to provide greater clarity and consistency within and between the various Regulations as well as responding to policy developments since the original Regulations were made, and reflecting changes in the organisation of the NHS following a review of the Department's Arms Length Bodies.

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 4 of the Health and Social Care (Community Health and Standards) Act 2003.

4.2 **Part 2** of the Regulations amends the National Health Service (General Medical Services Contracts) Regulations 2004 (SI 2004/291).

4.3 The amendments set out in regulation 2 make a number of changes, additions and deletions to the definitions in the 2004 regulations. The majority of these are required to underpin the amendments made elsewhere in Part 2 of these Regulations

- 4.4 The NHS (Pharmaceutical Regulations) 1992 (SI 1992/662) are being revoked and replaced from 1st April 2005 by the NHS (Pharmaceutical Regulations) 2005. In consequence it is necessary to make a number of changes to the 2004 Regulations. These are set out at Regulations 3 and 4(7)(b), (12), (13) and (14)(c).
- 4.5 Regulation 4(2) bans the use of national rate (087x), premium rate (09xx) and personal numbers starting with 070, for the purposes of general medical service contracts. This is to prevent patients having to pay any more than a local call rate for contacting their practice by telephone.
- 4.6 Regulation 4(3) lays down the requirements for the inclusion in General Medical Service Contracts of services involving the supply of medicines etc as part of the out of hours service. From April 2005 PCTs will be required by directions to use their powers to enter into arrangements for primary medical services which ensure that patients have appropriate access to supply of medicines during the out of hours period. This amendment lays down the conditions under which the provision of such services may also be included in GMS contracts if the PCT and the contractor so agree.
- 4.7 The Regulations allow for the introduction of an electronic transfer of prescriptions. This provision will enable GPs to submit electronically a prescription form or repeatable prescription to a dispenser nominated by the patient. Significant changes to the Pharmaceutical Regulations govern the dispensing of medicines etc, when electronic prescriptions are used. Until this service is introduced or where patients do not have a nominated dispenser, patients and doctors will continue to rely on paper prescription forms. The necessary amendments are set out in regulations 4 (4 -6), (7)(a)(ii), (8), (9), (10)(a) and (c) to (e), (14)(a), (14)(b),(17) and (18).
- 4.8 The provision of drugs by instalments is extended to include the supply of diazepam (regulation 4(5)(d)(i)).
- 4.9 From April 2005 GMS contractors in all PCT areas are permitted to issue repeatable prescriptions. Regulations 4(7)(a)(i) and 5 therefore repeal the requirement that contractors can only provide repeatable prescribing services if they hold a contract with a PCT listed in Schedule 9 to the Regulations.
- 4.10 Following changes to the Misuse of Drugs Regulations and the Prescription Only Medicines (Human Use) Order restrictions on the prescribing of controlled drugs or unlicensed medicines by supplementary prescribers are removed (regulation 4(10)(b)).
- 4.11 Following the Department of Health's review of its arms length bodies it has been decided to transfer functions of the National Clinical Assessment Authority (NCAA) (which is to be disbanded) to the National Patient Safety Agency. Regulation 4(15) makes the necessary change to the reference to the NCAA.
- 4.12 The Quality Information Preparation Scheme included as an enhanced service in the new GMS contract agreement comes to an end on 31 March 2005. Provision for this scheme is therefore removed from Schedule 6 to the 2004

Regulations (regulation 4(16)).

4.13 Regulations 4(19) & 4(23) require contractors who are companies limited by shares to notify the Primary Care Trust of a change of director or secretary and enables the PCT to terminate the contract if untrue information is given about the compliance of that director or secretary with the conditions set out in regulation 5 of the 2004 Regulations

4.14 There has been a lack of clarity about the status of a GMS contracts in the event of the death of the mandatory medical practitioner required under regulation 4 of the 2004 Regulations. Amendments are made to clarify the position for the benefit of patients, practice staff, other partners and the PCT.

Regulation 4(20) enables the PCT to vary a contract so that it may continue for an interim period following the death of a medical practitioner in a two handed practice where the remaining contractor is not a medical practitioner.

Regulation 4(21) provides that a contract with an individual medical practitioner shall terminate 7 days after that practitioner's death unless arrangements have been made for it to continue for a further short period.

4.15 Regulation 4(22) enables a Primary Care Trust to continue a contract for a limited period with a medical practitioner who no longer meets the conditions in regulation 4 if:

- (i) the reason for that failure is an interim suspension or health suspension under the Medical Act 1983,
- (ii) adequate arrangements are in place to provide clinical services during the period of suspension, and
- (iii) immediate termination is not necessary on grounds of patient safety or to protect public funds.

4.16 Regulation 4(24) clarifies that the grounds for termination of the contract in paragraph 113 of Schedule 6 to the GMS Contracts Regulations only apply to partners, shareholders and directors who join the contracting body after the start of the contract in respect of circumstances which arise after they have so joined (prior circumstances being covered by paragraphs 85, 86 and 112).

4.17 **Part 3** of the Regulations makes amendments to the National Health Service (Personal Medical Services Agreements) Regulations 2004 which mainly parallel those made to the GMS Contracts Regulations and other minor drafting amendments. In addition, regulation 8(21) provides that the definition of insurance in paragraph 113 of Schedule 5 to the PMS Agreements Regulations also applies to paragraph 114.

4.18 **Part 4** of the Regulations amends the National Health Service (Performers Lists) Regulations 2004 to amend references to Scottish legislations and replace references to Part 1 of the Sexual Offences Act 1997 (which has been repealed) with references to Part 2 of the Sexual Offences Act 2003.

4.19 **Part 5** makes transitional arrangements for contractors who already have telephone numbers that will breach the ban imposed by these regulations. Such

contractors will be required to vary or terminate their existing telephone arrangements in accordance with directions from the Secretary of State.

5. Extent

5.1 This instrument applies to England only.

6. European Convention on Human Rights

6.1 Not applicable.

7. Policy background

7.1. The NHS Confederation and the General Practitioners Committee of the BMA (“GPC”) reached agreement on a new contract for the provision of primary medical services by doctors. This was published in the document “The new GMS contract 2003 – Investing in General Practice” in February 2003. This agreement called for a change in the regulatory framework for the provision of primary medical services by doctors from the current statutory arrangements made with individual general practitioners to one based on contractual arrangements with practices. The primary legislation necessary to implement this agreement was included in Part 4 of the Health and Social Care (Community Health and Standards) Bill. These measures were the subject of full debate during passage of the Bill through Parliament in October and November 2003.

7.2 The Regulations set out in section 2 above represent the bulk of the secondary legislation, brought into force between February and April 2004, to bring about the new scheme for primary medical services.

7.3 Amendments are now required for three main reasons:-

- i. experience with the regulations has revealed areas where greater clarity would assist those who need to be guided by them;
- ii. policy in some areas has developed in the intervening months;
- iii. NHS organisational changes

7.4 The changes to regulations in respect of the death of a medical practitioner in single-handed or two person partnerships (i.e. regulation 4(20) to (21), are examples of the first of these areas. Regulations 4(4) to (6) etc. enabling the use of the ETP service is an example of a new policy area.

7.5 These Regulations are important in that they are a mechanism for new policy to improve the provision of primary medical services and in that they demonstrate a willingness to make changes to improve the usability, consistency and clarity of secondary legislation for the benefit of those that have to use primary care legislation.

7.6 The Department has consulted the NHS Confederation and the GPC on the content of these Regulations and they have signified that they are content with

the changes that are included.

8. Impact

- 8.1 A Regulatory Impact Assessment has not been prepared for this instrument, as it has no direct impact on business, charities or voluntary bodies. As indicated a number of changes relate to parallel changes made by the National Health Service (Pharmaceutical Regulations) 2005, a partial RIA has been completed in respect of those Regulations.
- 8.2 GMS and PMS contractors will need to procure changes to the software used by their computer systems if they choose to use the ETP service. Software changes to support national initiatives of this type are primarily funded by the National Programme for IT rather than by the individual practices.
- 8.3 There is no impact on the public sector.

9. Contact

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