EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (PRIMARY MEDICAL SERVICES) (MISCELLANEOUS AMENDMENT) (No.2) REGULATIONS 2005

2005 No. 3315

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) (the GMS Regulations);
ii. National Health Service (Personal Medical Services Agreements) Regulations 2004 (SI 2004/627) (the PMS Regulations); and
iii. National Health Service (Pharmaceutical Services) Regulations 2005 (SI 2005/641) (the PhS Regulations).

2.2 The amendments reflect legislative changes introduced in other areas, in particular in respect of the provision of pharmaceutical services, amends the requirements regarding the information that must be contained in certain clinical documents and make other minor miscellaneous changes

2.3 The Regulations also revoke Article 105 of the General Medical Services and Personal Medical Services Transitional and Consequential Provisions Order 2004 as a consequence of the amendments made.

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

3.1 This instrument revokes a provision in the General Medical Services and Personal Medical Services Transitional and Consequential Provisions Order 2004, which disapplied certain provisions of the GMS and PMS Regulations. The House of Lords Statutory Instruments Merits Committee commented in their 15th Report about the Department's need to extend one particular transitional power (Article 105) in the 2004 Order (see "C. SI 2005/518 General Medical Services and Personal Medical Services Transitional and Consequential Provisions (Amendment) Order 2005). The Committee expressed the view that the original policy objective had been imperfectly achieved.

3.2 This instrument removes the requirement that had been disapplied under the 2004 Order. Consequently, this disapplication provision is no longer necessary. Further explanation is provided in section 7 below. The revocation is included in these Regulations in reliance on the power in section 126(4) of the National

Health Service Act 1977 as it is considered an appropriate consequential provision.

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 Service Act 1977.

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

i. changes that are required following the introduction of the PhS Regulations;
ii. changes that are required following the commencement of the Civil Partnerships Act 2004;
iii. changes to the definitions of "repeatable prescribing" and "batch issue"
iv. miscellaneous changes.

PhS Regulations 2005

4.3 The PhS, GMS and PMS Regulations all contain provisions relating to the rules that apply to those who wish to dispense medicines and drugs under the NHS. These rules extend to contractors who wish to dispense drugs and medicines as part of primary medical services (i.e within general practice). Such service provision by primary medical services contractors tends to occur when the normal provision of these services by chemists in the area is considered to be inadequate for reasons of distance and accessibility. GPs who dispense drugs and medicines ("dispensing doctors") may be authorised to do so either under the provisions of the Ph S Regulations or under the provisions of the GMS or PMS regulations.

4.4 The PhS Regulations, which came into force in April 2005, introduced, amongst other things, significant changes to the rules that apply to dispensing doctors, the main one being a requirement for the PCT to approve the premises from which dispensing services are provided ("premises consent"). The changes being made to the GMS and PMS regulations bring the provisions that apply to dispensing doctors into line with those that apply under the Ph S regulations. This means that whichever authorisation route a dispensing doctor relies on, the requirements will be the same.

4.5 The provisions making these changes can be found at regulations 5, 7(2-4), 11 and 13(3-6).

Civil Partnerships Act 2004

4.6 The Civil Partnership Act 2004 introduced the new legal relationship of "civil partnership" and provides for the legal recognition of such partnerships across many walks of life.

4.7 The GMS and PMS Regulations currently refer to the term "spouse" in relation in two areas. Firstly in defining the term "immediate family member" and secondly in relation to the maintenance of a register of gifts made to those providing or performing services under a GMS/PMS contract. In both places where the term "spouse" is used the provisions are extended to include civil partners. These changes have been discussed with DTI.

4.8 The provisions making these changes can be found at regulations 2(3), 7(7), 8(3) and 13(9).

Repeatable Prescriptions and Batch Issue

4.9 The GMS Regulations and the PMS Regulations both currently include, at Schedule 1, templates setting out the format that must be used by computer systems that produce repeatable prescriptions and the associated batch issue form. These templates included a requirement to print the name of the primary medical services contractor on these forms. However, the GP computer system suppliers and the Prescription Pricing Authority (PPA) have not been able to amend their computer systems to provide or assimilate this information. Consequently, as a result of this technical problem, contractors are not able, in practice, to comply with the requirement to include the contractor's details on these forms. For this reason the requirement (to include the contractor's details) was disapplied by virtue of Article 105 of the General Medical Services and Personal Medical Services Transitional and Consequential Provisions Order 2004.

4.10 The amendments made in these Regulations remove the requirement that the repeatable prescription forms and batch issue forms should be in the format set out in the Schedule (which included the requirement that the contractor's name should be included). Instead, there is imposed a requirement that the forms will be in the format set out in specific, identified documents issued by the PPA, which format does not include a requirement to include the contractor's name. There are not technical "software" difficulties in complying with this requirement. Consequently, there is no longer any need to disapply the provisions relating to the format of these documents.

4.11 The provisions making these changes can be found at regulations 2(2), 2(4), (6), 7(5), 8(2), 8(4), 12, 13(7), 14 & 15.

Miscellaneous Amendments

4.12 In summary these are as follows:-

i. Optometrists are added to the list of healthcare professionals who may be supplementary prescribers. This follows changes to the Medicines for Human Use (Prescribing) Order 2005. Regulations 2(5) and 8(5) refer.

ii. The current Regulations impose restrictions on those with whom a PCT may enter into a GMS or PMS contract for the provision of primary medical services. Amongst those excluded is anyone who has ever been removed from the office of charity trustee or trustee for a charity or who has ever been removed, under the provisions of the Law Reform

(Miscellaneous Provisions) (Scotland) Act 1990 (which relate to powers of the court to deal with the management of charities) from being concerned in the management or control of any body. This "lifetime ban" is now considered disproportionate and is reduced to a ban of five years. Regulations 3 and 9 refer.

iii. A minor drafting change has been made to regulation 22 (Finance) of the GMS Regulations and regulation 13 (Finance) of the PMS Regulations that more accurately reflects in the Regulations the wording of the primary legislation. Regulations 4 and 10 refer.

iv. Contractors who maintain the records of their patients on computer system are obliged by the Regulations to have regard to certain good practice guidelines published by the Department. An updated version of these guidelines was published on 29 July 2005 and the associated reference in the Regulations is now updated. Regulations 7(6) and 13(8) refer.

v. The current PMS Regulations require a PCT to consult the Local Medical Committee (LMC) when considering the question of excessive prescribing by a PMS contractor. The LMC is a body representing local GPs. A PMS contractor does not have to be a member of the LMC. In these circumstances, a regulatory requirement to involve the LMC in all cases is inappropriate. The amendment recognises that a PCT may wish to consult the LMC but further provides that it can only do so with the consent of the PMS contractor. Regulation 13(2) refers.

5. Extent

This instrument applies to England only.

6. European Convention on Human Rights

No statement is required.

7. Policy background

7.1 The entire legislative base for the delivery of primary medical services was revised from 1 April 2004 with the introduction of, amongst other things, the new GMS contract and the ending of the "pilot" status of PMS (making PMS a permanent feature of primary medical services contracting). This involved the introduction of a number of new Regulations including the GMS Regulations and the PMS Regulations.

7.2 A further significant change was the introduction within GMS of individual contracts between GMS practices and their PCTs, bringing about a similar discipline to that already in place in respect of PMS. In PMS, both under piloting and under its new "permanent" status, services are provided under "contracts" between a PCT and the service provider.

7.3 One consequence of this change is that, as the GMS and PMS Regulations change PCTs have to vary over 8,500 individual "contracts" to bring them into line with those Regulations. Consequently, the Department believes it is neither appropriate nor sustainable to issue amending regulations on an "as and when basis". For example, in a previous year eight separate amendments were

made to the old GMS Regulations. If this was to continue unchecked (and the changes, as normal, ripple into PMS) PCTs would be faced with up to 68,000 annual contract variations a year.

7.4 Consequently, we now look to issue consolidated amendments no more than twice a year (in the spring and autumn).

7.5 The attached draft regulations are the third in a sequence and reflect the planned autumn 2005 amendment. On this occasion, the Regulations contain little that reflects brand new policy and are, in general, a tidying up exercise. However, we believe that we should, nevertheless, proceed with them for the following reasons, they:-

i. update the regulations (and keep our commitment to DTI) in respect of the Civil Partnership Act 2004;
ii. bring back into line the dispensing provisions (for example "premises consent") in the GMS and PMS Regulations with the new provisions included in the PhS Regulations 2005;
iii. deal with a number of more minor matters in advance of potentially more significant changes that may be required in April 2006 as part of ongoing work between the NHS Employers and the General Practitioners Committee of the British Medical Association (GPC) to review the operation of the GMS contract;
iv. reinforce in the minds of stakeholders the principle of twice yearly, as opposed to "as and when", amendments;

7.6 The Department has carefully considered the House of Lords Statutory Instruments Merits Committee in relation to the extension of the transitional provision in Article 105. When the original 2004 Regulations were drafted placing the details of the relevant contractor on prescription and repeatable prescription forms was consistent with a move from a system of arrangements with individual doctors to one of "contracts" with providers of services.

7.7 In operational terms the change was not immediately required as the computer systems operated by the PPA contain sufficient details to enable the data from prescription forms written by individual doctors to be aggregated (through the use of individual doctor codes) to contractor (practice level) for financial monitoring purposes. The provision requiring the identification of the contractor on these forms was in anticipation of a potential move to the use of "contractor" rather then "doctor" codes within the PPA computer systems.

7.8 This change in the PPA software has not been made and this has meant that GP software system suppliers have not seen the inclusion of "contractor name" on computer generated computer prescription/repeatable prescription forms as a priority in a time of other pressing developmental requirements.

7.9 As the use of "contractor name" is currently not required for accurate data processing, rather than extend the transitional power for further periods the Department has removed the need for this item to appear on prescription and repeatable prescription forms. This has no impact on Departmental information systems or efficiency.

7.10 In making this change, the Department has also moved to address the problems caused by having two sources of information on the format of prescription and repeatable prescription forms. One within the Regulations and one on the PPA website.

7.11 The PPA has traditionally being the source of public information in relation to the format of prescribing forms. For example, they provide GP system suppliers with detailed specifications in respect of all computer produced prescription forms, this includes repeatable prescriptions and batch issue (forms that must always be computer produced). These detailed specifications are available electronically on the PPA website. GP computer systems comply with these PPA specifications.

7.12 This is a classic scenario of two documents (the Regulations and the PPA print specifications) attempting to be the definitive source of information on a topic. In reality, users look to the PPA website for their information rather than to the Regulations. The PPA information is also more user friendly in that it is more detailed and is set in an overall context. In looking at removing the requirement to print the contractor's details on prescription, and repeatable prescription forms the Department has addressed this duplication issue. In future, the PPA will continue to publish the required specification of these forms on its' website, so creating a single source of information for users. The mandatory use of these specifications is maintained via a detailed cross reference in the GMS/PMS Regulations.

7.13 The Department has consulted the NHS Employers, the GPC and the Pharmaceutical Services Negotiating Committee and they have signified that they are content with these changes being brought forward.

7.14 The Devolved Administrations have also being made involved in the development of these Regulations.

8. Impact

8.1 A Regulatory Impact Assessment has not been prepared for this instrument as it has no impact on private business, charities or voluntary bodies. The impact on the public sector is estimated to be less than £5m.

9. Contact

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