EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (PRIMARY MEDICAL SERVICES) (MISCELLANEOUS AMENDMENTS) REGULATIONS 2007

2007 No. 3491

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) (the GMS Contracts Regulations) - which set out the framework for General Medical Services (GMS) contracts, and
ii. National Health Service (Personal Medical Services Agreements) Regulations 2004 (SI 2004/627) (the PMS Agreements Regulations) - which set out the framework for Personal Medical Services (PMS) agreements;

The amendments update the various Regulations to reflect policy developments and associated legislative changes introduced since the original Regulations were made, or last amended. Regulations were last amended in June 2006 (SI 2006/1501)

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

3.1 None

4. Legislative Background

4.1 These Regulations amend the 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 National Health Service Act 2006.

4.2 The changes being introduced through this instrument address a small number of issues related to other areas of legislation and matters that have, over time, become out of date. In themselves, they do not introduce any new primary medical services policy. They cover the following matters:-

- those relating to the EU directive (2005/36) on the recognition of the qualifications of healthcare professionals;
- those relating to the Mental Capacity Act;
- changes to the published format of forms relating to repeatable prescriptions;
- those relating to the revised home oxygen service, and

- those relating to the Controlled Drugs (Supervision of Management and Use) Regulations (SI 2006/3148);

In addition, we are making minor amendments relating to insolvency law, dispensing under a PMS contract and the service of remedial notices and breach notices.

4.3 **EU Matters**

Regulations 2(b) and 5(b) introduce minor changes flowing from the EU Directive (2005/36) on the recognition of the qualifications of healthcare professionals. The directive itself has no direct impact on the GMS Contracts Regulations or the PMS Agreements Regulations. The Committee will be aware that the Directive is being generally incorporated into NHS legislation by the European Qualifications (Health and Social Care Professions) Regulations 2007 (SI 2007/3101) which make a number of consequential amendments to various Acts and statutory instruments which implement the existing regimes on the recognition of such professional qualifications. Amongst those amendments are the revocation of Article 20 of the General and Specialist Medical Practice (Education, Training and Qualifications Order 2003 [SI 2003/1250] and the consequential amendment of Article 8 of the same Order. Article 8 deals generally with the award and withdrawal of a Certificate of Completion of Training (CCT). Article 20 specified certain functions which could be performed by the Postgraduate Medical Education and Training Board (the Board) under article 8. Those Article 20 functions included the function of issuing a CCT to EEA nationals in certain circumstances. In the light of the revocation of article 20, article 8 is amended to remove reference to those (revoked) functions. The Board will continue to award certificates under article 8 but it will no longer issue such certificates in pursuance of any function under article 20. In view of these amendments made by the European Qualification Regulations, the definition of "CCT" in the GMS Contracts Regulations and PMS Agreements Regulations no longer needs to include reference to certificates issued in pursuance of that article 20 function.

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**

EU Directive 2005/36

7.1 EC Directive 2005/36/EC replaces EC Directive 89/48EEC on 20th October 2007. The Directive applies to all nationals of member states wishing to practice a regulated profession (a profession restricted by law to holders of specific

qualifications) in a member state other than where they obtained their professional qualifications.

7.2 The intention behind the Directive is to make it easier for qualified professionals to practise their professions in European countries other than their own, with a minimum of red tape but with due safeguards for public health and safety and consumer protection.

7.3 The changes amend the list of recognised qualifications by which GPs from EEA countries may work in the UK. The amendment to the GMS Contracts Regulations and the PMS Agreements Regulations reflect the revocation of article 20 of the General and Specialist Medical Practice (Education, Training and Qualifications) Order 2003 by regulation 53 of the European Qualifications (Health and Social Care Professions) Regulations (SI 2007/3101).

Mental Capacity Act

7.4 The Mental Capacity Act 2005 provides a statutory framework to empower and protect people who may lack capacity to make some decisions for themselves, for example, people with dementia, learning disabilities, mental health problems, stroke or head injuries. The Act enshrines in statute current best practice and common law principles concerning people who lack mental capacity and those who take decisions on their behalf.

7.5 The changes amend the GMS Contracts Regulations and the PMS Agreements Regulations in various places to amend references to "incapable adults" to reflect the preferred terminology of the Mental Capacity Act 2005 and also to reflect (and make use of) the range of individuals referred to in the Act who might be available to act on behalf of an adult who lacks capacity.

7.6 Amendments are made to Schedule 6 of the GMS Contracts Regulations at: paragraph 15, Application for Inclusion in a list of patients; paragraph 17, refusal of application in list of patients or for acceptance as a temporary resident; paragraph 18, patient preference of practitioner; paragraph 19, removal from the list at the request of the patient; paragraph 39A, electronic prescriptions and nomination of a dispenser and paragraph 93, making of complaints.

7.7 Corresponding amendments are made to Schedule 5 of the PMS Agreements Regulations.

Repeatable Prescriptions

7.8 Medicines for patients on repeat prescriptions are ordered by GPs on forms ("batch issues" and "repeatable prescriptions") as approved by the Prescription Pricing Division of the NHS Business Services Authority. These forms were amended in 2006 and the new versions published on the Business Services Authority website alongside the former versions. These changes require GPs to use the new form from the date the amending regulations come into force.

Home Oxygen Services

7.9 In June 2003, the Department announced plans to modernise the home oxygen service, following an internal review of the service, which also took account of the recommendations of the Royal College of Physicians Working Group on oxygen therapy assessment and prescribing.

7.10 The changes, which came into force in February 2006, allow healthcare professionals, as well as GPs, to order oxygen therapy in the home. The FP10 prescription form should no longer be used for the prescription of oxygen therapy or when requesting home oxygen therapy for new patients. Like other clinicians, GPs should use the Home Oxygen Order Form. This form is sent direct to the service provider, who will use his technical expertise in deciding the equipment that will best meet patients' clinical needs.

7.11 The amendments are intended to eliminate the option of using FP10 forms for the prescription of home oxygen services. They include a definition of home oxygen services; amend Schedule 6, paragraphs 38 and 39 regarding the use of the home oxygen order form, and who may sign.

Controlled Drugs

7.12 The Controlled Drugs (Supervision of Management and Use) Regulations 2006 (SI 2006/3148) set out the requirements for designated bodies, including PCTs, to appoint an accountable officer. Those regulations also set out that officer's responsibilities as regards the safe, appropriate and effective management and use of controlled drugs, both where the management and use is by the designated body itself and also by any body providing services by arrangement with the designated body. Contractors already have an obligation under the contract to have an effective system of clinical governance. The amendments specify that this system of clinical governance shall include standard operating procedures in relation to the management and use of controlled drugs. They also impose a specific obligation to co-operate with the PCT in the discharge of the PCT's functions, or those of its accountable officer, under the 2006 Regulations.

Minor Changes

7.13 These are:

- **Insolvency -** a reference to NI insolvency legislation has been added to the existing English reference for completeness;

- **Dispensing under a PMS contract –** where the PCT has contracted with a Strategic Health Authority (SHA) to provide PMS it may currently provide dispensing services under the agreement simply with the consent of the Strategic Health Authority (SHA).The procedure by which an SHA may give such consent is much simpler than the procedure that must be followed by non-PCT contractors applying under the PMS Agreements Regulations, or by individual medical practitioners applying under regulation 60 of the National Health Services (Pharmaceutical Services) Regulations 2005 (the Pharmaceutical Regulations), for authority to

provide dispensing services. Applications by non-PCT contractors, or under regulation 60, require consideration of whether it is "necessary or desirable" to grant the application in order to secure in the neighbourhood in which the premises are located the adequate provision of pharmaceutical services. This is known as the "control of entry" regime. There is no requirement to take into account such considerations in the case of SHA consent and this process is therefore inconsistent with the overall "control of entry" regime.

In order to eliminate this inconsistency, the option of obtaining consent from the SHA to provide dispensing services is removed. PCTs that are providing PMS services and who wish to provide dispensing services under that agreement will from now on do so only in accordance with any individual authority held by their medical practitioners under regulation 60 of the Pharmaceutical Regulations .

This should not have any adverse effect on the delivery of dispensing services to patients. Enquiries of SHAs indicate that very few, if any, SHAs have given such consent and that most PCTs who are providing dispensing services under PMS Agreements already do so in reliance on individual authority held by their medical practitioners.

The amendments include transitional arrangements to allow any PCT contractors who may be providing dispensing services under SHA consent arrangements time to arrange (through their individual medical practitioners) for authority to dispense under Regulation 60 of the Pharmaceutical Regulations.

- **Service of remedial/breach notices** - this is a simple correction of a cross reference.

Consultation

7.14 In finalising the content of these amending regulations the Department have specifically consulted the General Practitioners Committee of the British Medical Association, the Dispensing Doctors Association and the Pharmaceutical Services Negotiating Committee. These organisations raised no objection to the content.

7.15 In addition, the devolved administrations have been made aware of the content of the Regulations.

Guidance

7.16 As the changes are relatively minor, the Department do not believe that any significant communication activity is required. Documentation will be published on the Departmental website linked to an announcement in the NHS CE bulletin "The Week". PCTs will all be provided with standard documentation to simplify amendments to GMS contracts and documentation will be shared with the General Practitioners Committee of the British Medical Association.

Consolidation

7.17 The Department remain cognisant of the committee's comments concerning consolidation made in relation to the last instrument that amended the General Medical Services Contracts Regulations and the Personal Medical Services Agreements Regulations (The National Health Service (Primary Medical Services and Pharmaceutical Services) (Miscellaneous Amendments) Regulations 2006 – SI 2006/1501). The Committee expressed specific concerns that those Regulations had not lead to a consolidation of the principal regulations. In replying to the Committee, Ministers undertook to return to the issue once the cross Government reply to recommendation 12 from your twenty-ninth report was finalised. The text of the recommendation was:

"The Government should put more impetus behind the process of consolidation and should aim, as a general rule, to publish consolidated electronic versions of each instrument following amendment."

7.18 In formally responding to this recommendation, the Government agreed that consideration should be given to formal legislative consolidation when changes are made to the principal instrument. The response was from the premise that such decisions would be on a case-by-case basis and would be made by departmental Ministers. The reply also addressed the use of informal consolidations such as the "Blue Books" published by DWP, adding that Department's will look at these solutions where it is feasible to do so and where the additional resources required are manageable.

7.19 In introducing the current set of miscellaneous amending Regulations the Department considered the possibility of consolidation, the resources required and other sources of information for those that might use the Regulations.

7.20 The Regulations are used to stipulate the mandatory elements of primary medical care contracts entered into between service providers and the Primary Care Trusts. In respect of GMS contracts, the Regulations and certain financial directions set out in a document know as the Statement of Financial Entitlement (SFE) set a rigid central framework for the contracts that must be followed. The primary reference documents used by providers and the PCT are, consequently, the Department's standard GMS contract template and the SFE.

7.21 Each time the Regulations are amended the Department issues electronically:

- a consolidated contract template;
- a standard variation notice for use by PCTs when amending existing contracts.

7.22 In addition, the Department periodically issues a consolidated electronic version of the SFE incorporating any amending directions issued since the last consolidation. The latest consolidation has been prepared and will be published at the beginning of December 2007 - the previous one consolidated the text as at 1 April 2006.

7.23 Personal Medical Services differ fundamentally to GMS in that the agreements (contracts) between the providers and the Primary Care Trusts are for local agreement subject to mandatory criteria set out in the PMS Agreements Regulations. Much of the mandatory elements mirror GMS and as such, the relevant parts of the GMS documentation can be copied locally.

7.24 The Department recognises that legal advisors and members of the public also have a legitimate interest in these documents. We would observe that legal advisors ought to have access to commercial consolidations through organisations such as Butterworths. However, we acknowledge that matters are not ideal for members of the public. Although we would point out that all the amendments to these Regulations are available, free of charge, from a single Departmental webpage via links to the OPSI website.

7.25 Despite the considerable steps the Department already takes to make the rules on primary medical care services available to those with a direct interest, the Department has considered the case for an immediate consolidation of these Regulations. The biggest single issue is the availability of suitable administrative and legal resource. As the Cabinet Office response indicated, the task of consolidation could be complex and resource intensive, involving not only the mechanical task of applying amendments but also reviews of policy objectives, a complete review of the drafting and ensuring that all cross-references to existing legislation remain correct. Alongside these general points there are issues with these particular Regulations that would increase the resource effort required to effect a consolidation:

- the amending regulations are short in comparison with the 200 pages of principal regulation;
- the principal regulations are not held on the SI template and would require complete recreation and associated proof reading;
- the recent consolidation of NHS primary legislation (NHS Act 2006) will add to the necessary changes;
- consolidated GMS Contracts Regulations would require consultation with the British Medical Association (the principle of legitimate expectation).

7.26 After very careful consideration of all the issues, the Department do not believe that it is appropriate for them to prepare consolidated regulations at this time.

8. Impact

8.1 An 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.