EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (PRESCRIBING AND CHARGING AMENDMENTS RELATING TO PANDEMIC INFLUENZA) REGULATIONS 2009

2009 No. 2230

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

2. Purpose of the instrument

2.1 These Regulations ease the restrictions on ordering two named antiviral drugs during an outbreak of pandemic influenza, adapt two standard General Practitioner (GP) contracts to enable – and in some cases require – GPs and their staff to order these drugs under a new voucher system, and modify the charging regime for these two drugs so that all NHS supply of them through authorised channels will be free of charge.

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

3.1 Yes. These Regulations breach the '21 day rule' for reasons explained in paragraphs 7.8 to 7.10 below.

4. Legislative Context

4.1 Most primary medical services in England are provided on the basis of one of two forms of standard GP contract between GP practices and Primary Care Trusts (PCTs): a general medical services (GMS) contract; or personal medical services (PMS) agreement. Provision for both these types of agreement is made in Part 4 of the National Health Services Act 2006 and Regulations under that Part.

4.2 A number of standard terms and conditions for GMS contracts and PMS agreements are set out in two sets of Regulations: the National Health Service (General Medical Services Contracts) Regulations 2004 ("the GMS Regulations"); and the National Health Service (Personal Medical Services Agreements) Regulations 2004 ("the PMS Regulations"). The GMS contract is generally speaking the more prescriptive of these two types of agreement, but in relation to prescribing and dispensing, both sets of Regulations – and so both types of agreement – contain provisions imposing detailed obligations on GP practices, in particular with regard to the way in which authorised prescribers are to prescribe medicines.

4.3 These include limitations on the prescribing of what are sometimes known as 'scheduled drugs' (not to be confused with scheduled drugs in the context of misuse of drugs legislation). In the current context, 'scheduled drugs' are drugs that appear in the Schedules to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004

("the Drugs Regulations"). Although, as the title of these Regulations indicates, they are made under powers relating to GMS contracts, under the PMS Regulations, the scheme in the Drugs Regulations has also been adopted for PMS agreements.

4.4 There are two types of scheduled drugs: a list of those drugs which GMS and PMS practices are simply not entitled to prescribe under any circumstances, sometimes called the 'black list', which is in Schedule 1 to the Drugs Regulations; and a list of those drugs that GMS and PMS practices are only entitled to prescribe in limited circumstances, sometimes called the 'grey list', which is in Schedule 2 to the Drugs Regulations. Two of the drugs on the 'grey list' are the influenza antiviral drugs oseltamivir and zanamavir – currently marketed under the brand names, Tamiflu and Relenza.

4.5 Another feature of the standard terms for both GMS contracts and PMS agreements is that where drugs are ordered as part of treatment offered under the agreement, with the exception of home oxygen supplies, they have to be ordered on a standard NHS prescription form, known as the FP10. Generally speaking, the GP practice is not allowed to use the FP10 for other purposes, but there is a blank part of the form which can be used for private prescriptions.

4.6 As well as providing a template to ensure that prescriptions meet the requirements of the Medicine Act 1968 ("the 1968 Act"), the FP10 prescription form (except for the blank part) provides access to NHS community pharmaceutical services, which are provided under arrangements made by Primary Care Trusts with retail pharmacies, appliance contractors and dispensing doctors. There are two statutory schemes under which these services are provided, both of which are set out in Regulations under the National Health Service Act 2006, they are known as arrangements for the provision of pharmaceutical services, and arrangements for the provision of local pharmaceutical services.

4.7 If medicines, drugs or appliance are ordered by a GP for dispensing under arrangements for the provision of either pharmaceutical services or local pharmaceutical services, a charge is generally payable, but there are some exemptions, which are set out in the National Health Service (Charges for Drugs and Appliances) Regulations 2000 ("the Charges Regulations"). The Charges Regulations also contain charging arrangements and exemptions from charging which relate to other avenues of NHS supply of medicines.

4.8 These new amendment Regulations are a further set of measures in the Department of Health's response to the pandemic of influenza caused by a new virus subtype that was first identified earlier this year in Mexico.

4.9 A key part of the Department's response is its arrangements for the distribution of antiviral drugs, and in particular of zanamivir and oseltamivir. These two antivirals are prescription only medicines (POMs). Under the 1968 Act and associated secondary legislation, POMs can only be sold or supplied in accordance with the prescription of a qualified prescriber. However, to

support the widescale supply of antivirals during an actual or imminent pandemic, amendments were made to medicines legislation in early May to enable the authorisation of the supply of antivirals by a person who is not qualified to act as a prescriber of POMs (a "non prescriber"), in accordance with a protocol approved by Ministers, an NHS body or the Health Protection Agency.

4.10 These amendments stipulated that the protocol must include criteria as to symptoms of and treatment for the pandemic disease. The effect of these changes was to enable a non prescriber to triage a patient through the protocol and if appropriate issue an authorisation to supply an antiviral. The amendments also created an additional exemption from the 1968 Act restrictions on supply in circumstances corresponding to retail sale. The new exemption allows for premises other than a registered pharmacy to be used as distribution points for supply of drugs under a protocol of the type mentioned in paragraph 4.9. Making use of these provisions, a protocol has been approved for treatment of the pandemic of influenza caused by the new virus subtype and a National Pandemic Flu Service has been set up, as part of which a national flu telephone and internet service has been established.

4.11 Where appropriate and in line with the national protocol, the National Pandemic Flu Service authorises an antiviral for a patient by issuing the patient with a unique authorisation number. In addition, each PCT has been directed by the Secretary of State to establish an 'antivirals distribution service'. When an antiviral is authorised through the National Pandemic Flu Service, Antiviral Collection Points (ACPs), which are holding stocks of antivirals from the national stockpile, supply the antiviral against the unique authorisation number.

4.12 While much of the population can be authorised an antiviral if appropriate through the national flu telephone or internet service, some patients for various reasons (for example they cannot access the internet or due to their age or symptoms) need to obtain their antiviral authorisation via a GP practice.

5. Territorial Extent and Application

5.1 This instrument applies to England only.

6. European Convention on Human Rights

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

7. Policy background

- ***What is being done and why***

7.1 Up until now, under the terms of the GMS contract or PMS agreement that GP practices have with their PCT, GPs and other authorised prescribers who work in GP practices have only been able to prescribe zanamivir and oseltamivir to

patients under a set of restrictive conditions set out in the grey list, which limit the categories of patients who can receive these antivirals.

7.2 The Department has decided to relax these conditions. These Regulations enable qualified prescribers at GP practices to order these two drugs for any of their patients without breaching the terms of the practice's contract/agreement with their PCT, provided they do so under the arrangements that the Department is making, together with PCTs, for the distribution of these drugs free of charge. In addition, if the arrangements under which the drugs are made freely available allow for this, non prescribers working for a GP practice, who have been approved by their PCT to do so, will also be able to order these drugs, by following the national protocol. Such arrangements will enable GP practices to play a key role in distributing antiviral drugs during an influenza pandemic without the need to take up the time of qualified prescribers on assessments that can be effectively and safely delegated to others.

7.3 The Regulations implement the following arrangements, which are based on a safety assessment in which the National Patient Safety Agency, the Royal College of General Practitioners and the Department were involved.

For prescribers-

Patients aged 13 years and over

If the patient is aged 13 or over, qualified prescribers have the option of ordering these drugs on a new voucher distributed by PCTs, or on the standard FP10 prescription form (which they will need to annotate 'ACP', the standard acronym for Antiviral Collection Point, to make clear that the order will not be dispensed as part of NHS community pharmaceutical services).

Patients aged 12 years and under

Where a patient is aged 12 years or under the voucher is compulsory. This is because it provides valuable assistance for prescribers in determining the correct dose (and for children under 1, on different formulations), which might not otherwise be so readily available. It is also needed to support the ACP in being able to select the appropriate product available.

Non prescribers-

If a non prescriber is working in a GP practice but is authorised by the Primary Care Trust to order these drugs, they will have to use the new vouchers.

7.4 Guidance is to be given to qualified prescribers to advise them to use the blank, right hand side of the prescription form so that, if a local retail pharmacy outlet is being used as the relevant ACP, it will reduce the potential for confusion between orders for drugs that are being distributed as part of the PCT's antivirals distribution service and orders that are being distributed as part of NHS community pharmaceutical services. Guidance will also

encourage prescriber to use computer generated FP10s for patients aged 13 years and over where possible as this will automatically embed the order in the patient's computer records.

7.5 Pharmacies will not be reimbursed by the National Health Service Business Services Authority for orders made on the new vouchers, or for right hand side FP10 orders of these antivirals that are annotated "ACP": they will instead send the voucher or form to their Primary Care Trust for appropriate remuneration for those specific dispensing activities.

7.6 Antiviral drugs will be issued through other NHS channels, for example by means of patient group directions or at walk-in centres, so the Charges Regulations have been amended to make sure that no prescription charges will be payable by patients who are intended to receive their antiviral medicines free of charge. It is likely that the new vouchers will also be used for distribution of medicines through these other channels, where the prescriber and the supplier are at different locations.

7.7 The voucher system could also be used for dealing with another emergency of a similar kind, if the need arose. Normally, any change to GMS contracts and PMS agreements necessitates PCTs instigating variations of over eight thousand GP contracts. These amendments have been designed so that if, in the future, different prescription-only antiviral medicines were needed to combat a pandemic causing a major threat to public health, all that would be needed is an amendment to the list of medicines in the Charges Regulations, and that change would automatically read through into GMS contracts or PMS agreements.

7.8 The reason for the urgency of the Regulations, and why the '21 day rule' is being breached, is to enable the full implementation of the new voucher system as quickly as possible. This voucher system is seen as an essential component of the Department's arrangements for the safe and effective distribution of influenza antivirals – allowing, as it will, a clear distinction to be drawn by both prescribers and suppliers between medicines ordered for distribution under the antivirals distribution service and those which are not. This is against a backdrop of very large numbers of patients being diagnosed as suffering from influenza caused by the new virus subtype and an immediate need to ensure that health care professionals have practical and legally secure systems in place to support the treatment they offer to their patients.

7.9 As matters stand, most GPs are in technical breach of their contract terms if they order oseltamivir or zanamivir for their patients in circumstances that do not satisfy the grey list conditions. They are also in technical breach of their contract terms if they order them on anything other than a standard FP10 prescription form. The Department is keen that the vital work of GPs and their staff is not interrupted by anxieties about technical legal difficulties that can be swiftly addressed.

7.10 Furthermore, orders for antivirals using the standard FP10 have led in some cases to double payment from the public purse for these drugs because

pharmacies and dispensing doctors have returned prescriptions for antivirals with other FP10 prescription forms sent to the National Health Service Business Authority for payment (i.e. for remuneration for their dispensing services and for payment for the drugs). The orders for antivirals that come free from the national stockpile should be sent to their PCT for appropriate remuneration (i.e. for remuneration for their dispensing services only – no payment for the drugs). The clarification provided by the Regulations and the guidance that accompanies them are an essential part of the package of ensuring that systems are in place as soon as possible to prevent inadvertent overpayment to pharmacies and dispensing doctors, and to ensure that they are provided with easily operable systems for obtaining the appropriate remuneration for their services.

- ***Consolidation***

7.11 There are no plans to consolidate the four sets of Regulations that these Regulations amend.

8. Consultation outcome

8.1 The Department consulted the General Practitioner Committee (GPC) of the British Medical Association about the original proposals upon which these Regulations are based, and has adapted the proposals in the light of the comments it received. The GPC's principal concern was to enable GP practices to continue to use the standard prescription form alongside the new vouchers (the original proposals suggested exclusive use of vouchers), and a compromise has been reached enabling continued use of the standard prescription form for patients aged 13 and over. The GPC have now expressed their contentment with the package as a whole. The approach to antiviral distribution has also been agreed with the Royal College of General Practitioners.

9. Guidance

9.1 The Department of Health is issuing guidance for PCTs, GPs and pharmacies as part of the implementation arrangements for the Regulations. It is making this available through normal communication channels.

10. Impact

10.1 There is minimal impact business, charities or voluntary bodies. GPs will have a new form, which will be mandatory in certain circumstances, but all involved in the supply of antivirals will benefit from the end to the current confusion over routes of supply for antiviral medicines and the new voucher will support GPs in selecting the correct medicine and dosage.

10.2 There is no negative impact on equality issues.

10.3 There is no negative impact on the public sector. These changes create clarity for the public sector organisations concerned – PCTs and the NHS Business Services Authority.

10.4 An Impact Assessment has not been completed.

11. Regulating small business

11.1 The legislation is not expected to generate any significant additional costs to small business. There are no significant effects on the costs of compliance to businesses and no adverse impact on any competition, equality or environmental issues.

12. Monitoring & review

12.1 The Department of Health will monitor these provisions for their effectiveness in supporting the health service response to a pandemic and review them once pandemic alert levels have returned to normal.

13. Contact

Claire Potter at the Department of Health (tel: 0113 254 6312 or email claire.potter@dh.gsi.gov.uk) can answer any queries regarding the instrument.