

Delivering the Out-of-Hours Review

***Securing Proper Access to Medicines
in the Out-of-Hours Period***

GUIDANCE for PCTs and Organised Providers

Gateway Number 4107

Delivering the Out-of-Hours Review

Securing Proper Access to Medicines in the Out-of-Hours Period

Purpose

This guidance summarises the key points of *Delivering the Out-of-Hours Review: Securing Proper Access to Medicines Out-of-Hours: A Practical Guide for PCTs and Organised Providers* which supports the implementation of the recommendations of the independent review of GP out-of-hours services (the Carson review¹) in respect of the availability of medicines out-of-hours.

Implementation will be supported by the Primary Care Trusts Supply of Medicines etc Out of Hours Directions 2005 (which will come into force in April 2005). These directions will enable PCTs to use their powers to arrange, as they consider appropriate, for drugs and appliances to be supplied to patients as part of primary medical services.

Background

In October 2000, ministers accepted the recommendations of the Carson Review which set out ways of improving the quality of these services in England. It recommended that, other than in exceptional circumstances, patients should be able to receive the medication they need at the same time and in the same place as the out-of-hours consultation, and that those medicines should be full courses and not 'starter packs'. This guidance have been issued in response to that recommendation.

¹ *Raising Standards for Patients. New Partnership in Out-of-Hours Care* Department of Health October 2000.
<http://www.out-of-hours.info/downloads/oohreview.pdf>

Action Points for PCTs

Action Point 1

Where patients' clinical needs are such that treatment should start without delay, they will need to be able to access the medicines they need at the 'same time and the same place'* as their out-of-hours consultation. PCTs will therefore need to develop systems that will allow this to happen, ensuring that the responsibility for locating a pharmacy or source of medicine supply will no longer lie with the patient or their representative but with the out-of-hours provider.

These systems are not meant to substitute for, or compete with, normal arrangements for prescribing and dispensing prescriptions. However, prescribing in the out-of-hours situation is different from prescribing during the day; it may be more appropriate if long-term decisions are taken after proper follow-up from those responsible for the patient's in-hour clinical needs. Moreover, because there are few situations in which treatment needs to be started without delay, a limited formulary of drugs can be used in an out-of-hours situation without detriment to the health of the patient.



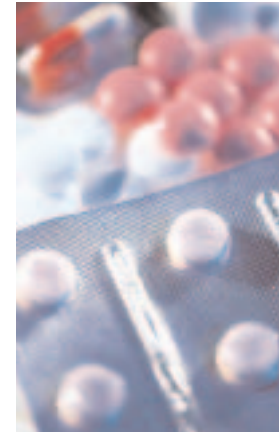
* Ideally, 'same time same place' means medicines are supplied as part of the out-of-hours consultation as for example with a One-Stop Primary Care Centre model, in which pharmacy services are co-located with primary care services throughout the OOH period. In implementing this guidance, however, PCTs will have to be realistic and make the best possible use of existing available resources and may need to use a nearby pharmacy.

Action Point 2

Only by working collaboratively with all appropriate service providers, will PCTs be able to secure services that deliver the Carson Review's medicines supply recommendations.

Supply of medicines via a pharmacy (or dispensing doctor^{*}) remains the preferred approach even during the out-of-hours period. But where this is not practical, PCTs may need to make alternative arrangements using their powers to arrange or provide primary medical services. It is for PCTs to decide how best to achieve this in their own locality. Options they could consider include:

- setting up a new pharmacy or extending opening hours and services from nearby pharmacies specifically for out-of-hours provision using the flexibilities available through Local Pharmaceutical Services schemes or the new pharmacy contract or, where that is not feasible
- supply through existing service providers such as NHS walk-in centres, minor injury units, hospital pharmacies or other existing facilities;
- arranging for medicines to be supplied by organised out-of-hours providers (e.g. a GP co-operative) as part of primary medical services (APMS) or by the PCT itself (PCTMS).



Arrangements must comply with all relevant legislation on the supply of medicines.

** Dispensing doctors are able to supply medicines to their own patients. If they have chosen transfer responsibility for providing out-of-hours services they will need to make provision to be able to supply out-of-hours formulary medicines to their own patients in the same way as they supply medicines to their own patients in-hours. All the references to dispensing doctors in this Guidance should be read in the same way, namely as a reference to their ability to provide medicines to their own patients in the out-of-hours period.*

Action Point 3

Modernising access to medicines out-of-hours starts with a PCT stock-take of the existing local situation, paying particular attention to the realities of provision.

Demand for out-of-hours services varies dramatically through the week and across the year, and is often at its highest at those times (e.g. Sunday morning) when mainstream pharmacy provision is most difficult to access. When assessing existing local provision, PCTs will want to identify actual pharmacy opening hours (not just contracted hours).

Action Point 4

PCTs should develop a local formulary, endorsed by the appropriate local prescribing committee(s) which includes all the medicines listed in the new national out-of-hours formulary. A 'whole system' approach should be adopted, in which neighbouring PCTs collaborate to develop out-of-hours formularies which are consistent across the population covered by each Out-of-Hours Provider.

A new national out-of-hours formulary has been developed which identifies the minimum list of drugs and other items that patients should be able to access. It is available in Part XVIIC of the Drug Tariff.²

Medicines should be supplied in appropriate quantities for the condition being treated and comply with relevant legislation on packaging, labelling and patient information leaflets. Manufacturers' original packs should be used wherever possible. A full course appropriate to the presenting condition should be supplied, i.e. the amount that would otherwise have been prescribed. The use of starter packs is not appropriate.



² The Drug Tariff can be viewed at http://www.ppa.org.uk/ppa/edt_intro.htm

Action Point 5

It is essential that every organised out-of-hours provider has robust, auditable systems in place to cover responsibility, reconciliation, record keeping and disposal requirements for the drugs for which it is responsible.

Out-of-Hours primary medical services commissioned (or provided) by PCTs must comply with all national standards applicable to out-of-hours services (including the Out-of-Hours Quality Requirements). These standards include a requirement to put in place mechanisms to purchase, store and supply medicines in line with current legislation, licensing requirements and good practice. It is for PCTs to ensure that these standards are met. <http://www.npa.co.uk/>

Action Point 6

PCTs should ensure that, where necessary and appropriate, patients are able to receive the benefit of the advice of a pharmacist or dispensing doctor, although this need not be face to face.

Action Point 7

PCTs will need to ensure that all health professionals are able to access appropriate levels of pharmaceutical advice out-of-hours.

Where alternative arrangements for supply are used, both patients and the health professionals involved should, where appropriate, be able to receive the benefit of the advice of a pharmacist or dispensing doctor. Specific advice from Macmillan nurses and palliative care specialists has also been shown to be particularly valuable. Where these do not exist, PCTs should seek to develop sources of expertise in palliative care as part of their broader palliative care strategy. Systems should also be in place for those rare occasions where it may be necessary to call out a pharmacist.

Action Point 8

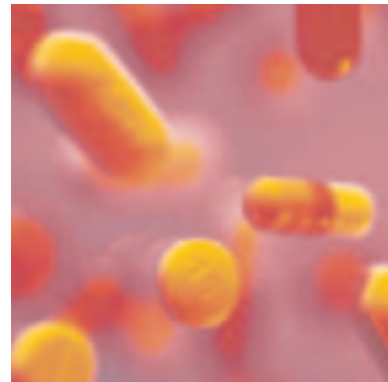
PCTs will want to consider and discuss fully, with all local stakeholders, how they can improve access to palliative care drugs in a way that best meets the needs of their community.

Action Point 9

As part of their stock-take, PCTs should seek to improve the quality of service delivery for palliative care patients and their carers by setting up systems that will ensure that they have prompt and easy access to medicines in the out-of-hours period.

There can be special problems in respect of the supply of medicines to palliative care patients in the community, whose condition can deteriorate or change rapidly. Many of these crises occur during the out-of-hours period and require urgent drug intervention and it is important that all clinicians have appropriate access to drugs (including controlled drugs) and a good understanding of which drug to use to best effect.

Effective solutions involve anticipating changes in these patients' needs. These may include a combination of: encouraging prescribers to prescribe sufficient drugs to take account of possible changes during the out-of-hours period; drugs prescribed on an 'as required' basis and left in the patient's home for administration by nurses; supply of drugs at an out-of-hours consultation; the use of sealed palliative care treatment packs that contain a locally determined range of symptom control drugs (but not controlled drugs); the use of existing palliative care and out-of-hours pharmacy schemes.



Action Point 10

For controlled drugs, a complete, documented and coherent audit trail should exist from stock room to patient. This should include drugs administered in the patients' home and drugs returned for destruction.

Doctors and pharmacists are legally permitted to possess and supply controlled drugs when acting in their capacity as such. As long as a doctor or a pharmacist undertakes the ordering and handling of such drugs, an organised provider does not require a licence. However, if these duties were to be undertaken by anyone else (e.g. an administrator) a provider (including a PCT) would require a Home Office licence.³ The regulatory framework which governs controlled drugs in the community may change in the light of the recommendations contained in the Fourth Shipman Report. Further information can be found at <http://www.the-shipman-inquiry.org.uk/fourthreport.asp>



³ For information on licences <http://www.homeoffice.gov.uk/drugs/licensing/index.html>

Action Point 11

PCTs should implement new arrangements for the recording and reporting of medicines prescribed and supplied out-of-hours

PCTs are recommended to ask the Prescription Pricing Authority (PPA) to assign their organised out-of-hours providers a unique code to appear on their NHS prescription forms. The PPA will then report monthly on items dispensed against the provider's prescriptions. Reports will go to the PCT that requests the code. If PCTs request more than one code for a provider, PPA will report separately on each code to the provider and PCT concerned.⁴

Where medicines are supplied direct to patients, PCTs should arrange for each supply to be recorded on a new standard supply form (FP10PREC), which includes the provider's unique code. Providers submit FP10PRECs to the PPA monthly, allowing the PPA to produce reports for the provider and its PCT, similar to that for items dispensed against prescriptions. Actual reimbursement mechanisms for medicines supplied will be for PCTs and providers to agree locally.

PCTs can obtain FP10PRECs (and prescription forms) for out-of-hours providers from Astron in the normal way. PCTs may permit blank FP10SS forms to be used by out-of-hours providers to produce supply forms, provided they are satisfied that the providers have the appropriate software to over-print the necessary annotations to identify the form as a FP10PREC.



⁴ Further information on how to obtain codes will be issued by the PPA: <http://www.ppa.nhs.uk>

Action Point 12

PCTs need to ensure that mechanisms are in place for collection of prescription charges and declaration of exemption status.

The NHS (Charges for Drugs and Appliances) Regulations 2000 are to be amended by April 2005 to ensure that the normal rules for prescription charges apply to medicines supplied (rather than dispensed) as part of primary medical services.

Action Point 13

By making appropriate local arrangements, PCTs will be able to improve the quality of their local data on actual community pharmacy opening hours and special out-of-hours schemes. This should include mechanisms for ensuring the information is kept up to date and available to NHS Direct.

Options to consider include commissioning NHS Direct to collect, validate and maintain data on its behalf; collecting the data itself and validating it with the Local Pharmaceutical Committee; sub-contracting with the Local Pharmaceutical Committee to collect the data. (However, PCTs should also note that as part of negotiations of the new contractual framework for community pharmacy it is proposed that pharmacies should be required to notify PCTs of their actual opening hours for provision of NHS services and give three months notice of a proposed change. This would assist PCTs themselves to maintain up to date information.)



The Directions

The directions enable PCTs to make arrangements as they consider appropriate for providers of out-of-hours primary medical services to supply medicines and appliances to patients using out-of-hours services who cannot reasonably be expected to wait until core hours to have a prescription dispensed. Before making such arrangements, PCTs must consider the effect on existing pharmaceutical services, and must keep the arrangements under regular review.



Other Sources of Guidance

A more detailed explanation of the action points and further advice about their implementation can be found in: *Delivering the Out of Hours Review: Securing proper access to medicines out-of-hours: A practical guide for PCTs and Organised Providers*.⁵

The Department of Health has also commissioned *A guide to good practice in the management of controlled drugs in primary care* (England). This is currently available in preview form.⁶

A new electronic guide, *Providing Medicines Out-of-Hours: Achieving Safe Practice* will be made available before the end of the year. It has been designed to help PCTs and providers of out-of-hours services understand the relevant medicines legislation and thus enable them to achieve safe and legal practice. This has been produced jointly by the National Pharmaceutical Association (NPA), the Pharmaceutical Services Negotiating Committee (PSNC), the Royal Pharmaceutical Society (RPSGB), the Company Chemists' Association (CCA) and the Department of Health.⁷

⁵ <http://www.out-of-hours.info/>

⁶ This guide is available in preview form from the National Prescribing Centre at http://www.npc.co.uk/background_for_cd.htm

⁷ *Providing Medicines Out-of-Hours; Achieving Safe Practice* <http://www.npa.co.uk>

Contact for Enquiries

All enquiries should be addressed to Helen Allanson
(Out-of-Hours Medicines Lead at the Department of Health)
at helen.allanson@clha.nhs.uk

Department of Health

December 2004