

Guidance on visits to pharmacies in England by external monitoring bodies

New legislation allows certain health care bodies to arrange visits to pharmacies for monitoring purposes. The Royal Pharmaceutical Society has produced the following guidance to assist pharmacists in England

Who can visit? Under the new pharmacy services regulations the local patients' forum, the Healthcare Commission, the primary care organisation (PCO) and some local authority bodies, such as the local authority overview and scrutiny committees, can arrange to visit any pharmacy in contract with the NHS. Pharmacists may also encounter other persons with powers of entry such as police chemist inspecting officers, customs and excise officers, trading standards officers and NHS Counter Fraud Services staff.

What is new? The new regulations introduce the right of external monitoring bodies to visit pharmacies and the responsibility to consider the recommendations in any of the reports produced as a result of such a visit.

What do I need to do?

- Be aware of the rights of the visiting bodies
- Ensure that any communication on a planned visit is acted upon promptly
- Ensure that reasonable notice has been given and that the visit is at a time when the health and safety of staff and patients will not be compromised
- If not stated, ask how long the visit is likely to take
- Ensure that the visit is conducted professionally and safely and protects patient confidentiality (Particular care is needed to protect patient details shown on computer monitors and prescriptions and to ensure that dispensing activity is not made unsafe by distraction or interruption.)
- Ensure, whenever possible, that the regular pharmacist and clinical governance lead is present at the time of the visit (If the regular pharmacist cannot be present and the visit cannot be rearranged, ensure the locum pharmacist is well briefed.)
- Respond to any opportunity to comment on a draft visit report
- Ensure that relevant personnel (eg, pharmacy support staff, line manager) are made aware of the visit
- At PCO inspection visits, the LPC may be invited to be present at the visit if the pharmacist requests it
- Be aware of the types of information each body may request and be prepared to challenge requests for information and/or documentation outside that body's remit
- Review the recommendations raised in any report with pharmacy staff, line manager and/or PCO and consider how they can be implemented
- If the visit would compromise the effective provision of health services or patients' safety,

Top tips

- Let the visiting organisation know when it is convenient to visit the pharmacy (eg, when the regular pharmacist is present and when the pharmacy is most quiet)
- At no time should patient safety and confidentiality be compromised
- Ask to see identification at the start of the visit if it is not offered
- Explain that interruptions are likely because the pharmaceutical service must continue
- Ensure that the purpose of the visit is clear and, if necessary, contact the review group leader beforehand to find out what documentation is likely to be needed during the visit
- Ensure that staff are well prepared for the visit and that relevant paperwork and documentation can be readily accessed during the visit
- Introduce relevant members of the team and ensure that they have prominent name badges
- Consider physical space in the pharmacy — where can the review team meet with minimal disruption and risk?
- Because members of the public may be concerned to see people inspecting a pharmacy, consider displaying a notice on the following lines: "This morning [—] is undertaking a routine inspection of this pharmacy and the services we provide. Please be assured that no patient confidential information will be disclosed during the course of this visit"
- If possible, ask for a verbal summary at the end of the visit and enquire when you can view the draft written report

privacy or dignity then the pharmacist should discuss any concerns with the person requesting the visit and ensure that adjustments are made to the visit plan to avoid any adverse impact on patients

- It is important for the pharmacist to ensure an opportunity to comment on any draft report (Any draft reports should be sent to the superintendent pharmacist of the organisation, whether small or large.)

Content of visits

PPI forum visits Patient and public involvement (PPI) forums have the power to "enter and inspect premises" owned or controlled by the PCO, local authorities, NHS trusts and primary care providers (such as GPs, dentists, pharmacists and opticians).

Anyone authorised in writing by a PPI forum may at any reasonable time enter and inspect a pharmacy providing NHS services. You should

ask to see written authority before making arrangements to go ahead with the visit.

The PPI forum can undertake both formal and informal visits. Most visits undertaken will be formal.

Formal visits

- Must be agreed to be undertaken at a forum meeting in public
- Must be agreed beforehand with the site to be visited — at least five working days' notice must be given
- Must consist of at least two forum members with an official card on every visit (There is no maximum number of visitors.)
- Will result in a formal report to the PCO or NHS trust

Informal visits

- Are carried out for the purposes of general research or as a fact finding mission
- Must be notified to the site to be visited by phone at least one hour beforehand
- Must consist of at least two forum members with an official card on every visit (There is no maximum number of visitors.)
- Will not result in a formal report to the PCO or NHS trust

Throughout any PPI visit the members visiting must not disrupt the services to patients in any way and must be made aware of any health and safety issues at the start of the visit. If forum members wish to speak to patients and/or carers in private then at least two people on the visit must be present at these discussions.

If the managers of a site to be visited believe that a visit would disrupt the health services they provide, or put patients' safety, privacy or dignity at risk, they can lawfully refuse to give forum members access to the site.

PPI forums would be encouraged, as good practice, to send a draft copy of the report to the site visited for comments before it is sent to the PCO/NHS trust. However, in some circumstances it may not be appropriate to do so.

Further information

Visits by a PPI forum have to comply with guidance set out by the Commission for Patient and Public Involvement in Health, available at www.cppih.org/documents/ForumHandbookDec04.pdf

PCO visits Reasons for PCO members to visit a pharmacy formally include:

- An annual clinical governance review
- A local pharmaceutical needs assessment
- Monitoring compliance with the new pharmacy contract (The Society's inspectors

may, in some cases, monitor the pharmacy contract on behalf of the PCO.)

- Investigating an unresolved complaint
- Looking at issues around poor performance

Visits should be formally notified to the pharmacy beforehand whenever possible and practicable. The PCO representatives may view some information or evidence, such as standard operating procedures (SOPs), at the visit. For monitoring purposes the PCO is required to determine whether the pharmacy has an appropriate SOP. It is not, however, required to carry out a detailed analysis of the content of an SOP as these are bespoke to the individual pharmacy. It is not a requirement under the terms of service for pharmacists to forward this documentation in advance of a visit. With some documentation there could also be issues of patient and commercial sensitivity should it be removed from the pharmacy premises.

Prior collection of evidence by the pharmacy team is good practice but the documentation should not leave the pharmacy premises before the visit.

Under Paragraph 37 of the chemists' terms of services, if the pharmacy contractor requests it, the local pharmaceutical committee (LPC) must be invited to be present at the PCO inspection of the pharmacy.

Further information

Paragraph 37 of the Chemists Terms of Services: The National Health Service (Pharmaceutical Services) Regulations 2005. Available at www.dh.gov.uk/PolicyAndGuidance/MedicinesPharmacyAndIndustry/fs/en
National guidance on monitoring the contractual framework has been produced for PCOs. It includes "top tips" and is available at www.primarycarecontracting.nhs.uk/114.php

Healthcare Commission visits The Healthcare Commission has several areas of interest in the performance of community pharmacy in the provision of health services to the public. The current statutory roles of the Healthcare Commission are:

- Assessment of the provision of health care, including public health, in the NHS and independent sectors
- Annual ratings for NHS trusts
- Regulation and annual inspection of independent health care
- Consideration of complaints which NHS trusts have not resolved
- Investigations into serious service failures
- Co-ordination of health care inspection by others

It is also to be given a new role in overseeing the arrangements for the monitoring of Controlled Drugs.

It seems likely that PCOs will assess the service provision of all those that they have contracts with, including community pharmacies, and they would potentially be the ones following up any areas of concern. The Healthcare Commission will assess PCOs, among other bodies, against its "Standards for better health" — 24 core standards and 13 developmental standards.

The PCO will complete a self-assessment and the Healthcare Commission could then request

more information on a random sample. The Healthcare Commission may, as part of its assessment of a PCO, request information from a contracted service either directly or indirectly through the PCO as the contractor or commissioner. This visit may be to corroborate something stated or said, to check the evidence and/or to monitor against the standards.

In most cases, pharmacists would be notified of a visit in advance and would be expected to make time to communicate fully with the commission members who carry out the visit. If the visit is intended to be carried out at a time that is inconvenient to the pharmacist (eg, when the pharmacist is on holiday), the date should, where possible, be rearranged.

The commission will also carry out improvement review visits targeted at selected themes such as substance misuse, tobacco control and services for children in hospitals. If a pharmacy is involved in a particular area, perhaps as an enhanced service, then it may be asked for more information or visited as part of the improvement review. The assessor who carries out such visits will have an identity badge.

Further information

"Standards for better health". Available at www.dh.gov.uk/assetRoot/04/08/66/66/04086666.pdf

Local authority OSC visits Since January 2003, local authority overview and scrutiny committees (OSCs), set up in local authorities with social services responsibilities (county councils, London borough councils and unitary authorities), have had the power to scrutinise health services as part of their wider role in health improvement and reducing health inequalities for their area. They can visit NHS organisations, and those providing services to NHS organisations, as part of this scrutiny function.

How the overview and scrutiny function operates is a matter for local choice. It can take many different forms. Committees can be based on particular functions (eg, social services, education) or be thematic (eg, social exclusion, regeneration). They may be politically proportionate or the full council (or parent committee) could agree, with no member present voting against, to waive this requirement to maximise involvement. Overview and scrutiny responsibilities may parallel departmental structures, executive members' portfolios or policy committee responsibilities, or be designed deliberately to cut across these to support a joined-up perspective and avoid the creation of a permanent watchdog for specific executive members or policy committees. Each overview and scrutiny committee could divide into smaller task groups to study and report back on a particular topic. There may also be a central co-ordinating committee. There are choices too about the frequency of meetings, their location and format (eg, whether and how to involve co-optees and the public).

Duties placed on NHS organisations, including pharmacies, in relation to OSCs include:

- Providing information to the OSCs when requested
- Consulting on substantial developments and variations in services

- Attending OSCs and responding to committee recommendations

Further information

Overview and Scrutiny of Health — Guidance. Department of Health, July 2003. Available at www.dh.gov.uk/assetRoot/04/06/62/38/04066238.pdf

A guide to overview and scrutiny committees in England for Local Pharmacy Leaders, NPA, Apr 2004

Working with local authorities: a background briefing for local pharmacy leaders, NPA, May 2004

Feedback mechanisms on visits

Pharmacists could ask those undertaking visits whether a feedback or evaluation sheet is available for them to complete.

PPI visits A pharmacist who has any concerns following a PPI visit should initially contact to the PPI forum itself. Any reports or recommendations from the PPI have a period of consultation so there should be an opportunity to address any misunderstandings then. If the above actions do not solve the grievance then the pharmacist should approach the head of public involvement at the primary care organisation.

PCO visits A pharmacist who has a concern or complaint about the visit should raise it via the PCO's complaints channels. Each PCO may have a different set-up in relation to complaints so the pharmacist will need to know whom to approach within their locality.

Healthcare Commission visits A sample of those organisations visited by the Healthcare Commission will be asked to complete an evaluation. General feedback can be forwarded via feedback@healthcarecommission.org.uk.

Complaints can be sent to Lea Pickerill, Healthcare Commission, Finsbury Tower, 103–105 Bunhill Row, London EC1Y 8TG (tel 020 7448 9413).

OSC visits Any complaints the pharmacist has about a visit from a local authority overview and scrutiny committee should be made to the local authority in which the OSC sits. The local authority will have a defined complaints procedure which will take the complaint through the various internal mechanisms to try to solve it.

If this is not satisfactory the complaint can be taken to a local government ombudsman at www.lgo.org.uk/contact.htm. The local government ombudsmen investigate complaints of injustice arising from maladministration by local authorities and certain other bodies. There are three local government ombudsmen in England, each dealing with complaints from different parts of the country. They investigate complaints about most council matters including housing, planning, education, social services, consumer protection, drainage and council tax. The ombudsmen can investigate complaints about how the council has done something. But they cannot question what a council has done simply because someone does not agree with it.

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