

Clinical governance requirements for community pharmacy

March 2012



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Introduction

In October 2011 the New Medicine Service and targeted MURs were introduced to the community pharmacy contractual framework (CPCF). Amendment of the clinical governance requirements of the CPCF was the final element of this package of changes to the CPCF.

The clinical governance requirements contained within paragraph 26, Schedule 1 of the National Health Service (Pharmaceutical Services) Regulations 2005, as amended (referred to in this document as the 2005 Regulations) have been updated by the [National Health Service \(Pharmaceutical Services\) Amendment Regulations 2011](#) (Statutory Instrument 2011/2136) (the 2011 Regulations). Transitional arrangements are in place to allow time for community pharmacy contractors that were on a PCT's pharmaceutical list on 30 September 2011 to become compliant with the requirements by 31 March 2012. Pharmacies that are included on a PCT's pharmaceutical list on or after 1 October 2011 must comply with the new requirements straight away.

What is clinical governance?

Clinical governance is a system through which healthcare providers are accountable for continuously improving the quality of their services and safeguarding high standards of care, by creating an environment in which excellence in clinical care will flourish.

Why is clinical governance important?

- It's about being accountable, taking professional responsibility, having the right systems and processes in place and about continuously improving what we do.
- It is a fundamental element of healthcare practice. It is a continuing process not an event.
- It is relevant to everyone – from counter assistants to technicians, pharmacists and pharmacy contractors.

The changes to the clinical governance requirements will bring community pharmacy in line with the clinical governance arrangements for other healthcare professionals. It is expected that compliance with the new clinical governance requirements will help to prepare the profession for the new commissioning architecture of the NHS, where primary care providers will need to demonstrate certain quality standards. The changes are not intended to be overly burdensome for community pharmacy.

This document explains the requirements that came into effect on 1 October 2011, as well as the existing requirements. In some cases templates are provided that contractors can use and adapt, or the document will signpost to existing resources. The document also outlines the rationale for the changes so that community pharmacy contractors and PCTs can put the changes into context. Most community pharmacy contractors already provide high quality services and will not have to drastically alter their way of working, as the amendments reflect best practice. Compliance with the changes will further demonstrate and embed quality and accountability in every interaction with patients and members of the public.

The document is structured to reflect paragraph 26, Schedule 1 of the 2005 Regulations and will reference the specific requirements of the paragraph. The use of the word 'approved' in the paragraph means that there are certain additional things that community pharmacy contractors must comply with and these 'approved' particulars are issued by the Secretary of State for Health.

The clinical governance requirements of the CPCF should be implemented in conjunction with any General Pharmaceutical Council (GPhC) standards, or guidance for pharmacists or pharmacy owners.

1 Patient and public involvement programme

1.1 Practice leaflet

“a requirement that the pharmacist should produce in an approved manner a practice leaflet containing approved particulars in respect of his pharmacy,” (paragraph 26(2)(a)(i), Schedule 1).

The original requirements for practice leaflets were issued in the approved particulars on 15 October 2008. They were updated in March 2012 to reflect changes to the details relating to accessing NHS Direct services. The approved particulars can be found in appendix 1.

The only change to this requirement is the need to ensure that a pharmacy’s practice leaflet contains the updated text relating to NHS Direct. However, the new requirements on publicising NHS services (see section 1.2) may also necessitate a change in the wording of practice leaflets.

It is important that the practice leaflet is kept up to date to ensure patients receive the correct information about the pharmacy and the services offered. In order to maintain its accuracy, amendments should be made as and when required. It is recommended that every time you review the services available from your pharmacy you also check that the practice leaflet is up to date, as the leaflet needs to reflect the services. As outlined in the approved particulars, pharmacies must list or describe NHS services available at the pharmacy, including advanced but not necessarily enhanced services. This is to avoid undue burden on pharmacy contractors to review the leaflet every time commissioning of enhanced services changes.

It is important to remember that under the NHS identity guidelines, use of the NHS identity is strictly controlled. Further information on the NHS brand guidelines for contractors is available on the [NHS Identity website](#).

A template practice leaflet is available on the [PSNC website](#).

1.2 Publicising NHS services

“(ii) a requirement that the pharmacist publicises the essential services and any advanced services that are available at or from the pharmacist’s pharmacy,

(iia) a requirement that where a pharmacist publicises the essential services or any directed services that are available at or from the pharmacist’s pharmacy (whether the pharmacist is producing their own publicity material or advertising services in material published by another person), the pharmacist does so in a manner which makes clear that the services are funded as part of the health service,” (paragraph 26(2)(a), Schedule 1).

Contractors are required to publicise the essential and advanced services that are provided at or from their pharmacy. They are not required to publicise any enhanced services that they provide but may wish to do so as this would be useful for patients, members of the public and other health and social care providers. As with the practice leaflet, it is recognised that enhanced services may only be commissioned for a limited time and there should not be an undue burden on pharmacy contractors to review the leaflet every time there are changes to this type of service.

The requirement has been extended to ensure that when contractors publicise the essential and directed services (i.e. advanced and enhanced services) available at or from the

pharmacy, it is clear that the services are funded by the NHS. This means that while they are free for the patient at the point of the service, it should be clear that these advanced and enhanced services are in fact paid for by the NHS and not the pharmacy. The intention of this change is to enable patients and members of the public to understand which services are commissioned by the NHS and which are provided privately. Contractors should review current and future publicity campaigns to ensure they comply with this new requirement. This requirement covers all forms of publicity media including posters, practice and other leaflets, radio and TV advertising.

There may be occasions where the community pharmacy provides a service both under the NHS and also privately. For example, a community pharmacy is commissioned by its PCT to provide influenza vaccinations to at-risk patients and also provides private vaccinations to people who do not fall into one of the at-risk groups. In this instance, the contractor could use the wording of the national flu campaign as the basis for the advert and could then add wording saying that patients who are not eligible under the NHS could receive a flu vaccination privately.

Pharmacies will want to be aware of the NHS identity guidelines when preparing publicity materials related to NHS services. The guidelines state that a pharmacy cannot use the NHS logo on pharmacy promotional or advertising materials; however it may be used, in line with the guidelines, on leaflets and posters that contain only information about NHS services provided. Further information on the NHS brand guidelines for contractors is available on the [NHS Identity website](#).

1.3 Patient satisfaction survey

“a requirement that the pharmacist should undertake an approved patient satisfaction survey annually, in an approved manner,” (paragraph 26(2)(a)(iii), Schedule 1).

Contractors have been required to undertake an annual patient satisfaction survey since April 2005, the aim being to seek the views of patients and members of the public using the services provided by the pharmacy (essential, advanced and enhanced services), which contractors can then use to improve and develop service provision. The approved particulars can be found in appendix 2.

The survey is a valuable opportunity to assess how well the pharmacy is performing from a patient's perspective and to improve its services. The information will be useful to demonstrate the value of services when commissioners are considering new services or the decommissioning of existing services. Another business benefit might be that the pharmacists and pharmacy technicians may be able to use the information to plan their own continuing professional development (CPD), as suggested in the Centre for Pharmacy Postgraduate Education (CPPE) [guidance](#).

The original requirements for the survey were issued in the approved particulars on 22 March 2007. These have now been updated to incorporate additional requirements. The survey ([Annex A](#)) has not changed but the manner in which it should be undertaken has.

As can be seen from the approved particulars, contractors are required to:

- summarise the demographic information provided (questions 11-13)
- collate the responses to questions 1 to 9.

Responses should be analysed, strengths and areas for improvement identified and a report is to be produced that identifies:

- areas where the pharmacy is performing most strongly

- areas for improvement together with a description of the action that has been taken or is planned to address the issue.

Action should be taken to address issues raised by respondents where this is practicable and proportionate to the issue raised. For example, if a majority of replies suggested that the time that the patient had to wait for their prescriptions to be dispensed was unsatisfactory, the pharmacy should consider the staffing resource available and consider increasing this. If, however, the free text comments included adverse comments about the lack of availability of parking in the vicinity of the pharmacy, there may not be a solution to this which is within the control of the contractor.

A template to assist with the analysis will be available on [NHS Employers](#) and the [PSNC website](#), but the use of this is not mandatory.

The results of the survey must be published via one or more of the following options:

- In the pharmacy, as a leaflet or poster.
- On the pharmacy's website.
- On the pharmacy's NHS Choices profile (if and when this functionality is available).

The results of the survey will be a summary of the collated responses (for example the percentage of patients finding the waiting time satisfactory, or otherwise), together with the action taken and/or planned to be taken, to address any areas for improvement.

Community pharmacies are reminded of their duties under the Equality Act 2010, for example, producing the survey in large format for patients with impaired vision if requested. Further information on the Act can be found on the [Home Office website](#). The distribution of the survey needs to reflect the pharmacy's business profile, so should be distributed in such a way as to ensure that no cohort of patients are given undue prominence. For example, surveying only patients who have received MURs, and not those that have received an enhanced service. The survey forms should be distributed across the opening hours of the pharmacy. Where a large proportion of patients receive their medicines by home delivery, arrangements must be made to ensure that these patients are included in the distribution. The contractor must summarise the demographic information provided.

Contractors who own a number of pharmacies should note that a separate survey should be carried out for each of their premises and separate reports should be produced, although the contractor could undertake the processing centrally.

The questions in the approved questionnaire are not all appropriate for distance selling pharmacies¹. PCTs, LPCs and affected contractors may wish to discuss replacing questions with similar questions of more relevance to the mail order or internet business model of delivery of services.

1.4 Monitoring arrangements for owed drugs or appliances

“the pharmacist’s monitoring arrangements for drugs or appliances owed to patients but which are out of stock,” (paragraph 26(2)(a)(iv), Schedule 1).

This requirement remains unchanged.

¹ Distance selling pharmacies are businesses that provide pharmaceutical services wholly by mail order or internet and whose application was approved under Regulation 13(1)(d) of the 2005 Regulations.

Monitoring arrangements could involve keeping a record of all owing or out of stock medication, using the pharmacy's IT system or carrying out regular audits. The Royal Pharmaceutical Society (RPS) has an [owings audit toolkit](#) available to members.

The requirement within clinical governance to have a process for monitoring these 'owings' will help contractors identify when owings are outside of their control. For example, a difficulty in sourcing the item due to supply problems or an item is not one the community pharmacy routinely stocks. They should also assist contractors to minimise the number of times they are unable to fulfil a prescription, by identifying where the reason for the owing is within their control.

Contractors are required to provide patients with a written note of any drug or appliance which is owed, and to inform the patient when it is expected that the drug or appliance will become available (**paragraph 10(d), Schedule 1**).

1.5 Approved complaints system (no longer covered in these Regulations)

Paragraph 26(2)(a)(v), Schedule 1 has been omitted from these new Regulations as the requirement to operate a complaints system is covered by paragraph 32, Schedule 1 (which was inserted on 1 April 2009). This amendment should therefore be considered to be a technical amendment only, and contractors should continue to ensure that their complaints system meets the requirements of the [Local Authority Social Services and National Health Service Complaints \(England\) Regulations 2009](#).

PSNC has published [guidance](#) on pharmacy complaints systems. The GPhC has produced [guidance](#) for pharmacists and pharmacy owners on responding to complaints and concerns.

1.6 Visits by Local Involvement Networks (no longer covered in these Regulations)

Paragraph 26(2)(a)(vi), Schedule 1 was revoked by the Local Involvement Networks Regulations 2008. This was also a technical change, because the obligation on contractors to cooperate with visits from Local Involvement Networks (LINKs) now sits in paragraph 1(e), Schedule 1.

1.7 Compliance with reasonable inspections or reviews by the PCT or any relevant statutory authority

"a requirement that the pharmacist co-operates appropriately with any reasonable inspection and review that the Primary Care Trust or any relevant authority wishes to undertake," (**paragraph 26(2)(a)(vii), Schedule 1**)

This requirement remains unchanged. PCTs and contractors will wish to note the link between this term of service and paragraph 37, Schedule 1 *inspections and access to information*.

The PCT or relevant statutory authority may wish to visit pharmacies on a regular basis and this may be preceded by a request to complete paperwork demonstrating compliance with the contractual framework. Although completion of a pre-visit self assessment (such as the CPAF previsit questionnaire) is not mandatory, it could aid the contractor and the PCT by minimising the amount of time needed for a monitoring visit.

It will be for the PCT or relevant statutory authority to determine the frequency of visits or reviews, but visits to pharmacies would normally be no more than once a year unless follow-up visits are required or there is cause for concern. The review may take the form of a self-assessment by the contractor, which may be followed up by a visit if necessary. As per requirement 37 (2) (b) the pharmacist can request that a representative from the Local Pharmaceutical Committee (LPC) is present during a visit, so visits should be arranged by appointment and allow sufficient time for the LPC to make arrangements.

During a visit a series of questions may be asked and requests may be made to see records that are required to be kept, where these may be disclosed without breaching confidentiality. The contractor should cooperate with the reasonable requests made by the PCT and the PCT should be mindful of the demands placed on the pharmacy staff during the visit, bearing in mind that the first priority for the contractor is delivering a safe and efficient service to the persons using the pharmacy.

(Note: the NMS and MUR service specifications now require the patient to give consent to the disclosure of the information about the NMS or MUR to the PCT for monitoring purposes, so records of these services carried out from 1 October 2011 may be disclosed, despite containing patient's confidential information.)

It is recommended that the PCT or relevant statutory authority allows four to six weeks' notice for the return of any paperwork involved in the review or inspection and should give three to four weeks' notice of an arranged visit. PCTs may carry out unplanned visits only where they have reasonable cause for concern, and not for routine monitoring, because of the requirement in the terms of service to allow the contractor to request that the LPC is present. If an unplanned visit is contemplated, it is suggested that the circumstances of the reasonable concerns are discussed with the LPC chief officer before the visit takes place, without disclosing confidential information, including the identity of the contractor.

1.8 Monitoring arrangements for compliance with the Disability Discrimination Act 1995

“the pharmacist’s monitoring arrangements in respect of his compliance with the Disability Discrimination Act 1995;” (paragraph 26(2)(a)(viii), Schedule 1)

This requirement remains unchanged. Contractors must comply with the Disability Discrimination Act 1995 (now superseded by the Equality Act 2010), but are not required to provide information to the PCT on assessments carried out, or of adjustments made to service provision. Ultimately it is for the courts to determine whether a community pharmacy has complied with the Act or not. A [resource kit](#) is available to contractors.

Contractors need to demonstrate that the pharmacy has monitoring arrangements in place to show its compliance with the Equality Act. For example, the contractor may have assessed the extent to which it would be appropriate to install hearing loops, or provide access ramps / wide aisles to allow wheelchair access. The contractor's assessment of his compliance with the Act should be documented.

2 Clinical audit programme

“a clinical audit programme (normally of five days), which includes at least one pharmacy-based audit and one other audit agreed by his Primary Care Trust in each financial year;” (paragraph 26(2)(b), Schedule 1).

Clinical audit programmes are an important part of practice and allow a pharmacy team to examine whether a service or procedure has reached a specified standard and then, where necessary, use the information to improve this service or procedure. It is important to re-audit to make sure the improvements have been achieved and so complete the improvement (audit) cycle.

Previously, the requirement was for each community pharmacy to undertake at least one pharmacy-based audit and one PCT determined multidisciplinary audit. This has been amended to remove the requirement for the PCT determined audit to be multi-disciplinary, as multi-professional uptake has not been as wide as expected.

Contractors may still choose the topic for their pharmacy-based audit and must complete a clinical audit on an area that has been determined by the PCT. This could include multidisciplinary audits where there is local support for these.

This change will help pharmacies and PCTs to develop an evidence base for the commissioning of services in the future, as well as improving the quality of current services.

It will normally take up to five days of staff time to complete the two audits. This time is cumulative and can be conducted over a number of days or weeks. It does not have to be a pharmacist who completes the audits.

An example of a pharmacy audit may be an audit of incomplete directions on prescriptions presented for dispensing (an 'as directed' audit). The PSNC has a guide to clinical audit available on its [website](#). Further guidance and audit templates can be found on the [RPS website](#) (members' area, log-in required).

The National Institute for Clinical Excellence (NICE) published [principles for best practice in clinical audit](#), which PCTs and contractors may find useful.

3 Risk management programme

3.1 Procurement and handling of stock

“arrangements for ensuring that all stock is procured and handled in an appropriate way,” (paragraph 26(2)(c)(i), Schedule 1).

This requirement remains unchanged. A standard operating procedure (SOP) covering this issue is required by the Responsible Pharmacist regulations.

3.2 Maintenance of equipment

“arrangements for ensuring that all equipment used in the provision of pharmaceutical services is maintained appropriately,” (paragraph 26(2)(c)(ii), Schedule 1).

This requirement remains unchanged. Contractors will wish to ensure that they have service contracts for the regular maintenance of equipment used in the provision of pharmaceutical services. PCTs may ask to see documentation relating to the maintenance of equipment in order to be satisfied that appropriate arrangements are in place or, for example, wish to see that monitoring records for fridge temperatures are being kept. It should however be noted that some of these matters relating to premises are also monitored as part of the GPhC's inspections, and PCTs should avoid duplication where possible.

3.3 Incident reporting

“an approved incident reporting system, together with arrangements for analysing and responding to critical incidents,” (paragraph 26(2)(c)(iii), Schedule 1).

There are new requirements for the incident reporting system that can be found in the approved particulars in appendix 3. Contractors are required to maintain a log of patient safety incidents, containing specified information, and to report patient safety incidents to the National Patient Safety Agency (NPSA) or its successor organisation through the online [National Reporting and Learning Service](#) (NRLS), using the NPSA defined levels of harm (see appendix 3).

An incident reporting system will help pharmacies when auditing and improving their practice. Increased reporting to the NRLS will enable the NPSA to identify risks by understanding the type and scale of errors. This will identify any trends that occur nationally and help with the development of learning.

A patient safety incident is any unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS-funded healthcare. The NPSA also sets out a definition of a 'prevented patient safety incident':

"A prevented patient safety incident is any unexpected or unintended incident that was prevented, resulting in no harm to one or more patients receiving NHS-funded healthcare. The incident could have been prevented by an action, an individual, timing, or by chance or luck. Note: This is sometimes referred to as a 'near miss' or 'close call'".

The content of the log of patient safety incidents should be used to help identify trends, or to highlight weaknesses in pharmacy systems and procedures. Appropriate staff are required to participate in the analyses of critical incidents. Such analyses should only involve relevant staff involved in providing NHS services that would have legitimate input into the analyses of the patient safety incidents. On some occasions this will need to involve counter staff and other times they will not.

There is some sensitivity about such records for dispensing errors, because under the Medicines Act 1968 a dispensing error could constitute a criminal offence. Until there are changes to the Medicines Act 1968, contractors must report through the anonymised arrangements to the NRLS and are encouraged to learn from their own investigations.

PSNC has developed a [reporting form](#) for patient safety incidents and prevented patient safety incidents (near misses). This matches the mandatory information required by the NPSA and so will make it easier to submit the report to the NRLS online via the [website](#). Contractors may use their own reporting forms to support NRLS reporting and for the information that should remain in the pharmacy patient safety incident log.

Examples of patient safety incidents include:

- No harm – impact prevented (near miss) – error noticed before medicine was handed over to patient.
- No harm – impacted not prevented – error noticed by someone other than pharmacy staff but none was used or taken.
- Low harm - error noticed by someone other than pharmacy staff, medicine used or taken but no harm done.
- Moderate – patient used or took medicine which caused noticeable side effects.
- Severe - patient used or took medicine which caused hospitalisation.
- Death.

PSNC has also produced further information on this topic and this can be found on their [website](#).

The NPSA has developed a programme of work looking at the key issues in medication safety that relate to community pharmacy. These include:

- a thematic analysis of patient safety incidents relating to medication: [Safety in doses](#)
- guidance on how the design and layout of the [dispensing environment](#) can make the dispensing process safer in community pharmacies.

3.4 Patient safety communications

"arrangements, including record keeping arrangements, for dealing appropriately and timeously with communications concerning patient safety from the Secretary of State(..) and the National Patient Safety Agency," (paragraph 26(2)(c)(iia), Schedule 1).

This is a new requirement that brings community pharmacies in line with the [Care Quality Commission's standard C1b](#) for all "provider" sectors. This requirement formalises what most contractors are already doing in regard to dealing with communications concerning patient safety. However, appropriate arrangements need to be in place to ensure that the information is received by the pharmacy. Dependent on the way the alerts are distributed by the PCT, this may include always having the fax machine switched on with paper in it, or regularly checking pharmacy email accounts. It is expected a record will be kept of what the contractor has done to implement or comply with the notice.

Standard C1b

Healthcare organisations protect patients through systems that ensure that patient safety notices, alerts and other communications concerning patient safety that require action, are acted upon within required timescales.

The Medicines and Healthcare products Regulatory Agency (MHRA) issues safety advice, warnings, alerts and recalls in respect of medical devices. The Department of Health (DH) also issues other communications concerning patient safety on behalf of the Secretary of State. Contractors are required to appropriately deal with all communications concerning patient safety, including keeping a record of what has been done to implement or comply with the communication.

'Appropriately' means that the community pharmacy has taken action to deal with the notice and alerts according to the nature of the alert. Many notices/alerts outline a course of action that contractors are required to follow. Many notices and alerts have an action date and contractors are expected to meet these deadlines in order to be considered to be acting in a 'timeously' manner, i.e. action is taken within the required timescale.

Example - Class 2 medicines recall

On 21 June 2011, the MHRA issued a class 2 drug alert for the recall of certain batches of Bayer plc Canesten 500mg pessary. Contractors were required to quarantine any stock of these batches and return it to the wholesaler from which it was originally obtained. Action was required within 48 hours.

In this instance appropriate action would be to remove any of the affected batches from the dispensary, dispensary staff to be alerted and the action taken to be noted and filed.

3.5 Standard operating procedures

"appropriate standard operating procedures, including standard operating procedures in respect of dispensing drugs and appliances, repeatable prescriptions and providing advice and support to people caring for themselves or their families," (paragraph 26(2)(c)(iv), Schedule 1).

This requirement remains unchanged. In order to ensure standard operating procedures (SOPs) are fit for purpose it is recommended that contractors undertake a review of SOPs every two years or sooner, if there is a material change that means one or more SOPs need updating.

Information about SOPs is available on the [PSNC](#) and [National Pharmacy Association](#) websites.

3.6 Waste disposal arrangements

“appropriate waste disposal arrangements (in addition to those required under Part 2) for clinical and confidential waste,” (paragraph 26(2)(c)(v), Schedule 1).

This requirement remains unchanged. The reference to Part 2 refers to the disposal service in respect of unwanted drugs (paragraphs 12 to 14, Schedule 1). The Department of Health issued [comprehensive guidance](#) (Gateway reference 15645) on the safe management of healthcare waste in March 2011, which contractors and PCTs may find useful.

This part of the terms of service therefore concentrates on the pharmacy having appropriate means of disposing of clinical waste (for example protective gloves, sharps, and swabs, if blood testing is undertaken) and for disposing of confidential waste (any paper form of patient-identifiable data including unwanted repeat prescription batch issues or repeat ordering forms, spare patient labels, hand written notes about patients etc.) Usually a suitable shredder will be required to dispose of modest quantities of confidential paper waste.

3.7 Clinical governance lead

“a clinical governance lead person for each pharmacy, appointed as such by the pharmacist (or that is the pharmacist), who is knowledgeable about both the pharmacy procedures of that pharmacy and the other NHS services that are available in the locality of that pharmacy,” (paragraph 26(2)(c)(vi), Schedule 1).

This requirement has been extended to clarify the requirements for the person who may act as the clinical governance lead person at each pharmacy.

The clinical governance lead is the main contact at the pharmacy, for the exchange of information on clinical governance between the PCT and the pharmacy. The clinical governance lead can perform this role at more than one pharmacy but it is expected they have good operational knowledge of the pharmacy.

PCTs and contractors will wish to note that the clinical governance lead does not have to be a pharmacist, but they would be expected to have the following:

- a good understanding of clinical governance, the clinical governance requirements and the ability to interpret and explain the Regulations to colleagues
- the authority to make decisions as appropriate for a clinical governance lead or report to a person who has that authority.

The clinical governance lead is expected to have knowledge of other NHS services that are available in the locality of that pharmacy. The extent of this knowledge is being able to refer patients to local GP practices, dentists and A&E departments. PCTs should ensure that contractors are able to access such information. This could be via the NHS Choices website.

A draft job specification for this post is available on the [PSNC website](#).

3.8 Safeguarding vulnerable groups

“(vii) appropriate child protection procedures,

(viii) appropriate vulnerable adult (as construed in accordance with section 59 of the Safeguarding Vulnerable Groups Act 2006(..) (vulnerable adults)) protection procedures,” (paragraph 26(2)(c)(vii) and (viii), Schedule 1).

This requirement has been extended by the addition of paragraph 26(2)(c)(viii) to cover vulnerable adults and is a result of the Safeguarding Vulnerable Groups Act 2006.

The contractor will be responsible for ensuring that relevant staff who provide pharmaceutical services to children and vulnerable adults are aware of the safeguarding guidance and the local safeguarding arrangements. This includes the reporting of concerns and so are alert to and act on indications that a child or vulnerable adult may be being abused, or at risk of abuse or neglect. PCTs will wish to ensure their contractors are aware of the local safeguarding arrangements and reporting procedures for concerns about children and vulnerable adults.

PCTs often require pharmacists to provide evidence of safeguarding training before being able to provide some services such as domiciliary MURs and sexual health enhanced services. CPPE provides open learning materials for use by pharmacists and pharmacy technicians, as well a local solutions workshop that is available for pharmacists and pharmacy technicians and PCTs to use to train staff.

3.9 Monitoring arrangements for compliance with the Health and Safety at Work etc Act 1974

“the pharmacist’s monitoring arrangements in respect of his compliance with the Health and Safety at Work etc Act 1974,” (paragraph 26(2)(c)(vii), Schedule 1).

This requirement remains unchanged.

Contractors must be able to show that they are monitoring health and safety. Contractors can monitor health and safety by, for example, doing spot checks, risk assessments, or by investigating any accidents or ill health suffered in the work place.

The enforcement of this Act is the responsibility of the Health and Safety Executive/Local Authority, and therefore the PCT does not monitor compliance. However, PCTs may wish to discuss how the pharmacists carry out their own monitoring arrangements during visits.

Contractors will find the [Health and Safety Executive \(HSE\) website](#) useful in ensuring they are complying with the requirements of this Act. In particular, the guidance [An introduction to health and safety](#) is a helpful document that explains the requirements and has guidance about different health and safety issues, as well as providing templates for a health and safety policy statement.

4 Clinical effectiveness programme

“a clinical effectiveness programme, which includes arrangements for ensuring that appropriate advice is given by a pharmacist in respect of repeatable prescriptions or to people caring for themselves or their families;” (paragraph 26(2)(d), Schedule 1).

This requirement remains unchanged. Contractors will contribute to improving the clinical effectiveness of prescribing through the management and dispensing of repeatable NHS prescriptions, when done in partnership with the patient, the prescriber and in particular, the Medicines Use Review service.

Patients or carers collecting repeat dispensing prescriptions must be counselled to ensure that they require all the medicines, that they are taking their medicines appropriately and to see if they are having any problems with them. Contractors will also wish to ensure that systems are in place to ensure appropriate self-care advice is given to patients by the use of protocols or SOPs.

5 Staffing and staff management programme

5.1 Induction for staff and locums

“arrangements for appropriate induction for staff and locums,” (paragraph 26(2)(e)(i), Schedule 1).

This requirement remains unchanged. Effective induction is essential to ensure staff compliance with pharmacy systems. It will encourage integration into the team, maximise productivity and realise the full potential of the employee.

Locum induction could consist of a checklist to go through:

- the day-to-day running of the pharmacy including opening hours, key holders, staff hours, break times, commissioned enhanced services
- the PMR system
- the whereabouts of SOPs, signposting information, contacts, enhanced service specifications, controlled drug register and the Responsible Pharmacist log.

Staff induction could cover:

- personnel and payroll matters
- an explanation of the terms and conditions of employment and company rules
- Health and Safety information
- physical orientation (where facilities are)
- organisational orientation (how they fit into the team)
- the company's culture and values, including 'raising concerns' policies
- a clear outline of the job role and responsibilities
- the learning and development opportunities available to them.

5.2 Training

“appropriate training for all staff in respect of any role they are asked to perform,” (paragraph 26(2)(e)(ii), Schedule 1).

This requirement remains unchanged. Staff should be given access to the training they need in a timely manner so that they are competent to complete the tasks they are expected to perform. Their progress and performance should be regularly reviewed and they should be given honest and constructive feedback (see the section 5.4 Development needs).

5.3 Qualifications and references

“arrangements for the checking of qualifications and references of all staff engaged in the provision of NHS services,” (paragraph 26(2)(e)(iii), Schedule 1).

This requirement remains unchanged. It is recommended that contractors check employees' qualifications and references before they commence employment. The checking of qualifications should apply to all members of staff whose declared qualifications are relevant to their employment.

For clarity, the contractor must also check the registration status of any pharmacists and pharmacy technicians that are employed or engaged. In the case of locums, the pharmacy should either check the registration themselves, or require the status to be checked by the locum agency as part of the contract with the agency. The registration status of pharmacists

and pharmacy technicians can be checked on the [GPhC website](#), but it is advisable to also check their identity using photographic identification such as a driving licence or passport.

Contractors will also wish to ensure that they have systems in place to ensure that all pharmacists and pharmacy technicians maintain their registration with the GPhC. This is of particular importance for superintendent pharmacists, as failure to renew their registration could mean that the body corporate is in breach of the Medicines Act 1968, and breaches of this legislation may lead to action under fitness to practise (suitability) provisions, which ultimately could result in removal from the pharmaceutical list.

5.4 Development needs

“arrangements for identifying and supporting the development needs of all staff engaged in the provision of services as part of the health service, including continuing professional development for registered pharmacists and registered pharmacy technicians and any necessary accreditation in respect of the provision of directed services,” (paragraph 26(2)(e)(iv), Schedule 1).

This requirement has been clarified to include the CPD of pharmacy technicians who are now required to be registered with the GPhC. The GPhC has issued [standards for CPD](#) for all pharmacy professionals.

All registered staff should be encouraged to engage in peer support programmes in accordance with the requirements of the GPhC's [Standards of conduct, ethics and performance](#), or where it would support a programme of continuous improvement within the pharmacy. One way of meeting this requirement is through staff appraisals and assessment of their competencies to provide contracted services, providing support where improvements are necessary.

5.5 Poor performance

“arrangements for addressing poor performance (in conjunction with a Primary Care Trust as appropriate),” (paragraph 26(2)(e)(v), Schedule 1).

This requirement remains unchanged. Contractors should have arrangements in place to deal with poorly performing staff. These arrangements could include:

- personal development plans
- identification of gaps in performance through regular staff appraisals with action planning
- access to training to remedy poor performance
- individual peer support and buddying/mentoring
- disciplinary procedures where appropriate.

5.6 Making a disclosure in the public interest policy (commonly known as ‘whistleblowing’ or ‘raising concerns’)

“arrangements (which must include a written policy) for ensuring that all staff and locums who, arising out of their employment with the pharmacist –

(aa) make what is a protected disclosure within the meaning given in section 43A of the Employment Rights Act 1996 (meaning of protected disclosure) have the rights afforded in respect of such disclosures by that Act, and

(bb) provide information in good faith and not for purposes of personal gain to the General Pharmaceutical Council or to a Primary Care Trust which includes an allegation of a serious

nature which they reasonable believe to be substantially true, but disclosure of it is not a protected disclosure within the meaning given in section 43A, have the right not to be subjected to any detriment or to dismissal as a consequence of that act;” (paragraph 26(2)(e)(vi), Schedule 1).

This is a new requirement in the community pharmacy terms of service, but the principles have applied elsewhere in the NHS for some time. If a person working within a pharmacy raises a concern with the pharmacy owner, or their representative, or a relevant external organisation particularly about public or patient safety, then they should be given protection from reprisals under the Public Interest Disclosure Act 1998. This is commonly referred to as ‘whistleblowing’. The law that protects whistleblowers is for the public interest, so people are encouraged to speak out if they find malpractice in the course of their employment, whether that is within the organisation in which they work, or in other organisations.

This requirement goes further than the Employment Rights Act 1996 and encourages disclosures to be made directly to the GPhC or PCT. The requirement applies the spirit of protected disclosure enshrined in the Employment Rights Act to a pharmacy setting. For clarity, locums are also entitled to make a disclosure.

The purpose of these new provisions is to require pharmacy owners to develop an open and safe environment within which members of staff and locums can feel comfortable about raising concerns reasonably and responsibly, without fear of exposure or victimisation. The whistleblowing policy is a vehicle for staff to raise concerns about malpractice within their own organisation as well as external organisations. Concerns should be raised about issues such as:

- threat to patient safety, for example irresponsible/illegal prescribing, dispensing, patient abuse, a professional whose health or competence is impairing their fitness to practise
- breach of a professional code of conduct, for example the Code of Ethics for pharmacists and pharmacy technicians
- criminal offence, for example fraud, theft, illegal diversion of drugs
- breach of a legal duty, for example failure to have a responsible pharmacist for each pharmacy
- inappropriate behaviour on the part of another employee or employees, for example breaching patient confidentiality, by discussing patient information with other staff members who have no legitimate interest in such matters
- danger to health and safety of the public or staff, for example having dangerously deficient electric equipment in use, knowing that there is a fault
- danger to the environment, for example irresponsibly and illegally putting returned medicines into the sewer
- cover up of any of the above.

The Social Partnership Forum (SPF) has published guidance for DH to help NHS organisations develop and implement a whistleblowing policy. This includes a template raising concerns policy and communications toolkit. You can download the guidance from the [NHS Employers website](#). Alternatively, PCTs may wish to share their policy with their contractors.

PSNC has further guidance on its [website](#). In February 2012, the GPhC also issued [guidance on raising concerns](#).

Further resources published by the RPS and Public Concern at Work, an independent charity specialising in whistleblowing, can be found on the [RPS website](#).

6 Use of information

The original wording of paragraph 26(2)(f), Schedule 1 has been substituted with the following two requirements.

6.1 Procedures for information management and security

“compliance with approved procedures for information management and security,” (paragraph 26(2)(f)(i), Schedule 1).

This clarifies that contractors are required to ensure they comply with the standards set out in the information governance toolkit (IGT) available on the [Connecting for Health website](#). There is little difference between this requirement and the previous wording of paragraph 26(2)(f), Schedule 1, particularly as most contractors will have undertaken a baseline assessment of their compliance with the standards in the IGT by 31 March 2010 and will have developed action plans to ensure they are working towards full compliance.

By 31 March 2011, contractors were expected to attain level 2 against each of the pharmacy information governance requirements. However, discussions continue between PSNC and the DH on the business continuity requirement (8-319), both the scope and realistic timescales for completing business continuity planning. To support contractors, PSNC will in due course publish a template business continuity impact document and plan.

6.2 Annual self assessment of compliance

“submission of an annual self assessment of compliance (to an approved level) with those procedures via approved data submission arrangements which allow the Primary Care Trust to access that assessment,” (paragraph 26(2)(f)(ii), Schedule 1).

This change formalises the requirement on contractors to submit annual self assessments by 31 March each year, and as stated above, for 2011 – 2012, pharmacies are expected to achieve level two on the IG Toolkit. The approved particulars can be found in appendix 4.

The requirements will be reviewed annually by DH, in consultation with PSNC, and generally be published by the start of the financial year in question. There may be occasions when there are amendments or additions to the IGT within the year. In these circumstances DH and PSNC will, depending on the nature of the change, agree a reasonable timeline when pharmacies need to comply by.

7 Premises standards

This is a new section to paragraph 26, Schedule 1.

7.1 Cleanliness of premises

“a system for maintaining cleanliness at the pharmacy which is designed to ensure, in a proportionate manner, that the risk to people at the pharmacy of health care acquired infection is minimised,” (paragraph 26(2)(g)(i), Schedule 1).

This is a new requirement. Although community pharmacies are relatively low-risk environments, good infection prevention and control are essential to ensure that people who use them receive safe and effective care. Effective prevention and control of infection must be part of everyday practice and be applied consistently by everyone working within healthcare.

For this requirement contractors are expected to maintain good housekeeping. For example, where appropriate (e.g. where there are increased risks of spreading infection, the use by staff of alcohol hand gel, tissues and surface cleaners. The use of the word 'proportionate' is important. It is not expected that contractors will be required to meet the same standards as surgeons in hospitals, so good standards of hygiene, keeping dispensing benches clean etc will be sufficient. But if the pharmacy is involved in vaccination schemes, or undertakes diagnostic testing involving phlebotomy, then higher standards of cleanliness will be appropriate.

As contractors expand the range of services they provide they should review their system for maintaining cleanliness to ensure it is proportionate to the risk of infection.

7.2 Appropriate environment

“arrangements for compliance, in the areas of the pharmacy in which patients receive NHS services, with any approved particulars that are designed to ensure, in a proportionate manner, that those areas are an appropriate environment in which to receive health care,” **(paragraph 26(2)(g)(ii), Schedule 1).**

This is a new requirement with the intention to ensure that the parts of the premises from which NHS services are provided must be recognisable to patients as premises from which high quality NHS services are available. Patients receive excellent health services and advice at their local community pharmacy and the physical premises should reflect a professional healthcare environment. The requirements for premises can be found in the approved particulars in appendix 5. Because this is a completely new area for the terms of service, contractors should consider these approved particulars alongside the guidance. The approved particulars try to balance maintaining an environment in which patients feel comfortable with an environment that is professional.

The prescription reception area should be easily recognised as such and not used for the display of non-healthcare related items. For example, you would not expect to find sweets and confectionary in this area.

In pharmacies where non-healthcare related goods are provided, to the extent that this can be achieved in a practicable and proportionate manner, there should be a buffer between the areas displaying non-healthcare related goods and medicinal products. This buffer area could display items that are related to healthcare such as sun tan lotions or dental care.

Contractors should note the requirement to ensure premises are seen by the public to be open for the provision of pharmaceutical services during core and supplementary opening hours. There have been examples of pharmacies that are not visibly open during their contracted opening hours, which is unacceptable and this requirement seeks to address this. The approved particulars are an attempt to balance accessibility for patients with ensuring the safety of staff. The only exception to this relates to distance selling pharmacies, as they are unable to provide essential services to persons at their premises.

If the pharmacy has a waiting area or seating available for customer use, the seating must be in good working order and appropriate for a healthcare environment. This means that contractors should ensure all seating is capable of being kept clean.

8 Implementing the approved particulars

The new and revised approved particulars do not come into effect until 1 July 2012. Until then, contractors should make any adjustments to their procedures. PCTs might also want to support their contractors during this period, so that the totality of the clinical governance framework is fully implemented from that date.

Appendix 1 – Clinical governance system acceptable to the Secretary of State: Pharmacy practice leaflet

Gateway number 17365

PHARMACY PRACTICE LEAFLET

The below outlines the requirements to fulfil paragraph 26(2)(a)(i)² of Schedule 1 to the National Health Service (Pharmaceutical Regulations) 2005.

Approved Particulars

The practice leaflet must include the following:

1. Name, address and telephone number of the pharmacy;
2. If owned by a company based elsewhere, the contact details for their head office;
3. Opening hours;
4. List or description of NHS services available at the pharmacy (including advanced, but not necessarily enhanced services);
5. Access arrangements for disabled customers;
6. NHS Direct details as follows: “When the pharmacy is closed, for any health problem advice and details of other health services, contact NHS Direct, 24 hours a day. Call 0845 4647 or visit www.nhs.uk/nhsdirect”;
7. Notice that the pharmacy is not obliged to serve violent or abusive customers;
8. Notice that the pharmacy complies with the Data Protection Act and the NHS code on confidentiality;
9. Detail of how to find out more about services offered, comment on those services, or make a complaint;
10. Contact details of the local PCT; and
11. The leaflet may refer to healthcare-related non-NHS services provided by the pharmacy, but if it does so, it must be under a separate heading “Other services we provide”, .

² Incorporating SI 683/2008

The leaflet must be printed using a plain font in minimum size 12 pt (the minimum size recommended by the Royal National Institute for the Blind), with sufficient contrast between print and background colour.

The leaflet must be branded with the NHS logo and the pharmacy descriptor line “Providing NHS Services” in the bottom right hand corner on the first page. The NHS logo must, as a registered trademark, be used in accordance with the NHS identity guidelines for pharmacies, available at: www.nhsidentity.nhs.uk A pharmacy/practice logo may be used as well, if the pharmacy has one.

The effective date for these approved particulars is 1 July 2012.

Appendix 2 – Approved patient satisfaction survey and manner in which it is to be undertaken

Gateway number 17365

PATIENT SATISFACTION SURVEY

The below outlines the requirements to fulfil paragraph 26(2)(a)(iii) of Schedule 1 to the National Health Service (Pharmaceutical Services) Regulations 2005.

Approved Particulars

1. Pharmacists must undertake a patient satisfaction survey (as set out in ANNEX A) annually.
2. If contractors add additional questions, they must be related to healthcare service provision.
3. The minimum number of returned surveys for analysis required each year is proportional to dispensing volume, as outlined in the table below:

Average monthly script volume (Items)	Minimum number of returned surveys
0-2,000	50
2,001-4,000	75
4,001-6,000	100
6,001-8,000	125
8,001- upwards	150

4. The questionnaire must be free from adverts.
5. The questionnaire must be accompanied by:
 - a) an explanation as to what it is for;
 - b) instructions on how to complete it;
 - c) options for it to be returned;
 - d) a description of what will be done with the responses provided.
6. There must be at least two choices as to how questionnaires can be returned. For example:
 - a) return it to the pharmacy;

- b) return it to a location other than the pharmacy;
 - c) reply electronically.
7. The survey must be distributed from the premises to which it refers.
 8. Surveys must be distributed only to persons who have received NHS services from the pharmacy.
 9. Surveys must be distributed in a way which reasonably reflects the pharmacy's business profile. For example:
 - a) it is unacceptable to survey all patients who have received an medicine use review (MUR), but none who have received an enhanced service;
 - b) surveys should be distributed evenly over the opening hours of the pharmacy, including weekends and extended hours where applicable;
 - c) where the pharmacy delivers a significant number of prescriptions to patients' homes, consideration needs to be given to ensure a suitable distribution of surveys to these patients.
 10. The pharmacy must summarise the demographic information provided and collate the responses to the nine mandatory survey questions. Responses should be analysed and strengths and areas for improvement identified.
 11. Where practicable action should be taken to address issues raised by respondents, in a manner that is proportionate to the issue raised.
 12. The pharmacy must publish the results of the survey. This report should identify the areas where the pharmacy is performing most strongly and the areas for improvement together with a description of the action taken or planned.
 13. The results must be published via one or more of the following options:
 - a) in the pharmacy, as a leaflet or poster
 - b) on the pharmacy's website
 - c) on the pharmacy's NHS Choices profile (if and when this functionality is available).

The effective date for these approved particulars is 1 July 2012.

Appendix 3 – Approved particulars for the incident reporting system

Gateway number 17365

INCIDENT REPORTING SYSTEM

The below outlines the requirements to fulfil paragraph 26 (2) (c) (iii) of Schedule 1 to the National Health Service (Pharmaceutical Services) Regulations 2005.

Approved Particulars

1. Pharmacies must have a patient safety incident log for all incidents as below. The log must capture the following information, where known. Some of this information is required by the National Patient Safety Agency (NPSA). Other information will need to be retained at the pharmacy for internal review.
 - a) date the form was completed, who it was completed by, their position and GPhC number (if any), date of the incident, time of the incident, who dealt with the incident, where the incident was a dispensing error who it was dispensed by and checked by;
 - b) patient's name and address;
 - c) patient's details - date of birth, sex, ethnicity any disabilities;
 - d) if it concerns a dispensing error, the type (drug, strength, quantity, dose, label or other)
 - e) describe the incident;
 - f) degree of harm (near miss, no harm, low harm, moderate harm, severe harm, death);
 - g) describe any action which prevented incident reaching patient or minimised impact on patient;
 - h) describe any apparent contributing factors;
 - i) describe any actions taken to prevent reoccurrence;
 - j) if a note has been put on the patient's record;
 - k) what were the underlying causes and if the new procedures will prevent occurrence;
 - l) patient follow-up - describe action taken with patient and patient's reaction/view of the incident.
2. Patient safety incidents must be reported to the National Reporting and Learning Service at the NPSA or its successor organisation.
3. Patient safety incidents must be reported using the NPSA defined levels of harm:
 - a) No harm – impact prevented. Any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to people receiving NHS-funded care;
 - b) No harm – impact not prevented. Any patient safety incident that ran to completion but no harm occurred to people receiving NHS-funded care;
 - c) Low. Any patient safety incident that required extra observation or minor treatment;

- d) Moderate. Any patient safety incident that resulted in a moderate increase in treatment and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care;
 - e) Severe. Any patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care;
 - f) Death. Any patient safety incident that directly resulted in the death of one or more persons receiving NHS-funded care.
4. Appropriate staff are required to participate in the analyses of critical incidents and the analyses must only involve relevant staff involved in providing NHS services who would have legitimate input into the analyses of the patient safety incidents.

The effective date for these approved particulars is 1 July 2012.

Appendix 4 – Approved particulars - Information governance programme

Gateway number 17365

INFORMATION GOVERNANCE PROGRAMME

The below outlines the requirements to fulfil paragraph 26 (2) (f) of Schedule 1 to the National Health Service (Pharmaceutical Services) Regulations 2005.

Approved Particulars

The overarching position is that community pharmacies must comply with required levels of confidentiality and compliance with the Data Protection Act set out in the Information Governance Toolkit. The requirements will be reviewed annually by the Department of Health, in consultation with the Pharmaceutical Services Negotiating Committee (PSNC), and generally be published by the start of the financial year in question. There may be occasions when there are amendments or additions to the Information Governance Toolkit within the year. In these circumstances the Department of Health and PSNC will, depending on the nature of the change, agree a reasonable timeline when pharmacies need to comply by.

For the year 2011/12 community pharmacies must comply with version 9 Level 2 of the Information Governance Toolkit on the Connecting for Health website. As part of doing so, they must submit annual information to the PCT or successor organisation to provide assurance that the pharmacy is meeting the required standards and to assess their information governance policies and standards.

They must have completed and submitted the template documenting such to their PCT by 31st March 2012.

Appendix 5 – Approved particulars for premises

Gateway number 17365

Clinical Governance

PREMISES

The below outlines the requirements to fulfil paragraph 26 (2) (g) of Schedule 1 to the National Health Service (Pharmaceutical Services) Regulations 2005.

Approved Particulars

This part of the terms of service requires pharmacy contractors to have a premises standards programme as part of their system of clinical governance. This premises standards programme must include the contractor's arrangements for compliance with any approved particulars, which have to be designed to ensure, in a proportionate manner, that the parts of the premises used for the provision of NHS healthcare are an appropriate environment within which to receive that healthcare.

The parts of the premises from which NHS services are provided must be recognisable to patients as premises from which high quality NHS services are available, should be generally clean and look professional, and literature on health and social care issues that is available should be up to date. Patients should be able to easily identify areas used for NHS healthcare, for example the prescription reception area and confidential consultation areas. Where practicable the areas used for NHS healthcare should be distinct from areas used for non-healthcare related services.

Separate from these particulars, contractors are required by the legislation to include, as part of their premises standards programmes, systems for maintaining cleanliness at their pharmacies which are designed to ensure, in a proportionate manner, that the risk to people at the pharmacy of health care acquired infection is minimised. The cleanliness requirements mentioned in these particulars are in addition to that separate obligation.

Contractors must ensure that:

1. The pharmacy (other than a distance selling pharmacy) is seen by the public to be open for the provision of pharmaceutical services, during its core and supplementary opening hours. Accordingly the premises should have the appearance of being open to members of the public who are outside the premises.
2. Where, for reasons such as security, the doors to the premises are kept locked during any core or supplementary opening hours, the pharmacy is laid out and organised to provide for the following:

- a. a member of staff must be posted immediately inside the door, or a hatch, so that members of the public seeking pharmaceutical services can see that there are staff on the premises available to provide pharmaceutical services (an arrangement whereby a doorbell is used to summon a response from a member of staff is not sufficient); and
 - b. the staff are to invite the member of the public to enter the premises, if this is necessary to preserve the confidentiality of any discussions, or if the facilities needed for the provision of pharmaceutical service are available only inside the premises.
3. The area of the premises from which NHS services are provided functions properly as a healthcare environment. This includes:
 - a. keeping the area where medicines are dispensed or sold clean;
 - b. ensuring that the amount of space available allows staff to perform tasks safely; and
 - c. ensuring the prescription reception area:
 - i. is easily recognisable as such and not used for the display of non healthcare related items,
 - ii. has appropriate facilities for signing the reverse of prescriptions, and
 - iii. has a notice about the NHS prescription charge.
4. In pharmacies where non health-care related goods are provided, there is, to the extent that this can be achieved in a practicable and proportionate manner, a buffer area between the displays of medicinal products and the non healthcare related items.
5. There are appropriate levels of privacy for conversations with patients.
6. If there is a confidential consultation area there must be a sign stating this. The consultation area or room must be:
 - a. clean and should not be used for storage of any stock (other than stock that is stored in closed storage units or stock that may be used, sold or supplied during a consultation – for example, hand wipes, emergency hormonal contraception, needle and syringe exchange stock etc.);
 - b. so laid out and organised that any materials or equipment which are on display are healthcare related; and
 - c. so laid out and organised that once a consultation begins, the patient's confidentiality is respected, and no member of staff who is not involved in the consultation is able to enter the area unless authorised by the pharmacist, such authority being given only if the confidentiality of the discussions during the consultation is preserved. Interruptions to the consultation must be kept to a minimum.
7. If the pharmacy has a waiting area or seating available for customer use, these are also appropriate for a healthcare environment. Any seating must be in good working order.

The effective date for these approved particulars is 1 July 2012.

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