Community pharmacy assurance framework – clinical governance pre-visit questionnaire

Service description

Pharmacies have an identifiable clinical governance lead and apply clinical governance principles to the delivery of services. This will include use of standard operating procedures; recording, reporting and learning from adverse incidents; participation in continuing professional development and clinical audit; and assessing patient satisfaction.

Definition of clinical governance

Clinical governance is a framework through which NHS organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish. There are seven key components: Patient and public involvement; clinical audit; risk management; clinical effectiveness programmes; staffing and staff management; education, training and continuing professional and personal development; and use of information to support clinical governance and health care delivery.

Completion of this form is required by NHS England. It covers matters that can be self-assessed, and apart from random checks for verification purposes, avoids the need for these matters to be covered during visits. Pharmacy contractors might find it helpful to refer also to the Contract Workbook published by the Pharmaceutical Services Negotiating Committee, when completing the questionnaire.

The terms of service are set out in Schedule 4 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, Statutory Instrument number 349 – http://www.legislation.gov.uk/uksi/2013/349/contents/made. Approved particulars released by the Secretary of State should be read alongside the terms of service - http://www.dh.gov.uk/health/2012/03/approved-particulars/. They cover additional requirements for:

- Practice leaflets
- Patient satisfaction survey
- Incident reporting
- Information governance
- Premises

Please complete the shaded boxes and return the form to [*insert AT officer details*] within 14 days.

Name of contractor …….. ODS code ……

Address of premises (including postcode)……..

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Service Indicator and Terms of Service (ToS) Reference	Pre-visit questions	AT comment / explanation	A HubNet Pharmacy
There should be a clinical governance lead for each pharmacy. ToS - 28(2)(c)(vii)	Who is your clinical governance lead?	There is a specimen job description available at www.psnc.org.uk/cg	Via the Team Builder system superintendents have their own unique login.
The clinical governance lead should be knowledgeable about both the pharmacy procedures of that pharmacy and the other NHS services that are available in the locality of that pharmacy. ToS - 28(2)(c)(vii)	Does the clinical governance lead have knowledge of the pharmacy procedures, and of the GP and dental surgeries nearby, and the nearest accident and emergency unit?	The information about other services may be known through local contact, or it may have been provided by the AT, or obtained from the NHS Choices website.	HubNet allows direct remote access to the pharmacy clinical logs, clinical diary, CPPQ survey, complaints and registers.
Patient and public involvement programme The pharmacy should produce, in an approved manner, and make available in an appropriate manner a practice leaflet. ToS - 28(2)(a)(i)	Do you have a pharmacy practice leaflet, containing the information required?	The information that must be included in the practice leaflet is set out in the approved particulars.	There is a designated practice leaflet within the system which allows a pdf, printable copy to be generated.
The pharmacy should publicise the essential services and any advanced services which are being provided at or from the pharmacy. ToS - 28(2)(a)(ii)	How do you publish the availability of essential services and any advanced services that you may provide from your pharmacy?	The AT may ask to see publicity during monitoring visits.	HubNet.io pharmacies have the ability to publish this information to the Voyager Health portal.

Where the pharmacy publicises essential or directed services (advanced and enhanced services) that are available at or from the pharmacy, the pharmacy should do so in a manner that makes clear that the services are funded as part of the health service. ToS - 28(2)(a)(iii)	Does all publicity for the essential, advanced and enhanced services provided by the pharmacy contractor make clear that these are funded as part of the NHS?	Remember that the NHS branding rules[1] do not permit the use of the NHS logo on promotional or advertising materials.	See above.
The pharmacy should undertake an approved patient satisfaction survey annually, in an approved manner. ToS - 28(2)(a)(iv)	When did you last complete the survey? If you have not yet carried out the survey, enter the month and year in which you expect to complete the survey.	The approved particulars set out the requirements for the survey.	There is a dedicated CPPQ survey module built into the system.
	When did you publish the results? If you have not yet published the results, enter the month and year in which you expect to do so.	Pharmacies are required to summarise the demographic information provided and collate the responses to the nine mandatory questions. The results must be published and a report produced to 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.	Pharmacies have the ability to download and print a summary of their yearly CPPQ survey.
	How have you publicised the outcome of the survey?	The results 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)	Every survey comes with the ability to print a poster summary of survey results.

[1] http://www.nhsidentity.nhs.uk/all-guidelines

Monitoring arrangements for medicines or appliances owed to patients, which are not in stock, should be in place. ToS - 28(2)(a)(v)	Do you have arrangements in place to monitor medicines or appliances owed to patients? Do you take action as a result of monitoring out of stock items? For example, is it possible to identify inconsistent prescribing patterns or failures in stock replenishment?	The AT may want to discuss these arrangements during the visit.	Within the Governance module the following SOPs are applicable: • Owings
An approved complaints system should be in place that meets the requirements of the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009[2]. ToS - 34	Has the pharmacy put in place arrangements for dealing with complaints? More information is available at www.psnc.org.uk/cg	The arrangements for dealing with complaints must be such as to ensure that— (a) complaints are dealt with efficiently; (b) complaints are properly investigated; (c) complainants are treated with respect and courtesy; (d) complainants receive, so far as is reasonably practical— (i) assistance to enable them to understand the procedure in relation to complaints; or (ii) advice on where they may obtain such assistance; (e) complainants receive a timely and appropriate response; (f) complainants are told the outcome of the investigation of their complaint; and (g) action is taken if necessary in the light of the outcome of a complaint.	Our complaints module is embeddable, i.e. it can be easily placed on a pharmacy's website, otherwise there is a link messaging service where an anonymous link can be directly sent to a pharmacist. This module has been built specifically for NHS complaints procedure.

[2] These regulations can be found at http://www.legislation.gov.uk/uksi/2009/309/contents/made

	Who is the 'responsible person' for ensuring compliance with the regulations?	The 2009 Regulations required each responsible body to designate a person to be responsible for ensuring compliance with the complaints arrangements. This will normally be the pharmacy contractor (if the pharmacy business is undertaken by a sole proprietor) or the Chief Executive of a body corporate, or one of the partners if the pharmacy business is undertaken by a partnership.	This can be taken from specific PMR modules, or this can be recorded within our system as a back up of this fails.
	Who is the complaints manager, who is responsible for handling complaints on a day to day basis?	This could be the contractor, or it could be a member of staff authorised by the contractor to ensure that day to day issues relating to complaints are dealt with	The Team Builder module contains a complaints module which allows remote control and monitoring from the superintendent.
	Do you have a leaflet outlining your complaints procedure, which is available to patients or other members of the public?	The AT may ask to see any information that is provided to patients or other members of the public, who want to know about your complaints procedure, during monitoring visits.	The complaints module allows the download of a generic NHS complaints leaflet which can be readily printed off and given to the patient.
	Do you maintain a record of complaints received (including the findings of any investigations and actions you have taken as a result)?	The AT may discuss complaints in general during monitoring visits. The AT will not ask to see individual complaints records, but may wish to be satisfied that you are keeping records, and are taking appropriate action.	See complaints module.
	What was the date of your last complaints Annual Report?	The 2009 Regulations require that you produce an annual report, which must be available to any person on request.	Annual complaints reports can be generated and downloaded form the complaints module.
	What was the date on which you sent the complaints annual report to the AT?	The annual report must also be sent to the AT as soon as reasonably practicable after the end of the year to which it relates (the year runs from April to March).	This can be submitted electronically to AT.

Monitoring arrangements in respect of compliance with the Equality Act 2010 are in place. ToS - 28(2)(a)(vii)	When did you last review your arrangements for accessibility to your pharmacy by people with a disability?	There are two aspects to the disability legislation – the first is the arrangements made for access to your premises, by persons who have a disability. The AT will be checking that you have arrangements in place in which you monitor your compliance with the disability legislation. For example, do you keep a log of complaints about lack or access; do you record and respond to comments made by persons with a disability about improvements that might be made? The AT will not be carrying out any assessment of whether persons with a disability can access the premises, but may discuss how you review your compliance with the legislation.	Our complaints module enables the anonymous submission of complaints to the superintendent this includes complaints about access. Our survey module is open to every patient whether disabled or not, this can be filled with suggestions the patient might have. The superintendent can review all governance remotely.
	Do you carry out assessments of patients, and keep these together with records of adjustments made in the course of supplying medicines?	This is the second aspect to the legislation – the assessment of disabilities and identification of adjustments necessary. The enforcement of the legislation is for the courts, not the AT, so the monitoring team will only wish to ensure that you give due consideration to your obligations. The AT may do this by discussing with you during monitoring visits your process for the assessment of patients, the adjustments that might be appropriate and records that are helpful. However, the AT will not attempt to suggest how you must act in order to meet your obligations.	See above.

Clinical audit programme A clinical audit programme (normally of five days) is in place, which includes at least one pharmacy based audit and one other audit agreed by the NHSCB in each financial year. ToS - 28(2)(b)	Which pharmacy based audit have you carried out in the last 12 months?	The AT may wish to discuss with you during monitoring visits the audit that you carried out, and if it is possible, to see the record of the audit, so long as there is no intrusion into confidential patient information.	Within the Quick Forms section there are template audits the pharmacist can use to get them started.
	Have you carried out the other audit proposed by NHS England? If not, please provide an explanation.		Within the Clinical Diary there is the ability to upload yearly audits.
Risk management programme Arrangements are in place to ensure that all stock is procured and handled in an appropriate way. ToS – 28(2)(c)(i)	Do you have a SOP which is signed by all relevant staff to say they have read it, understand it, and follow it?	Note, whilst a SOP is not required under the terms of service, the Responsible Pharmacist regulations do require appropriate SOPs. The NHS does require that there are arrangements to ensure stock is procured and handled in an appropriate manner, and the AT may wish to discuss the arrangements with all relevant staff.	Within the Governance module the following SOPs are applicable: • Ordering stock
All equipment used in the provision of pharmaceutical services is maintained appropriately. ToS - 28(2)(c)(ii)	Do you have service contracts for the regular maintenance of equipment used in the provision of pharmaceutical services?	The AT may ask to see documentation relating to the regular maintenance or for example, wish to see that you are keeping records of fridge temperatures.	Within the Governance module the following SOPs are applicable: • Equipment maintenance
An approved incident reporting system is in place, together with arrangements for analysing and responding to critical incidents. ToS - 28(2)(c)(iii)	Do you have a patient safety log that meets the requirements of the approved particulars?	The log must capture the information set out in the approved particulars. During monitoring visits, the AT may ask to see that you are keeping such records, but will not wish to examine individual records.	The HubNet system includes an error and near miss log.
	Do you report patient safety incidents to the National Reporting and Learning Service (NRLS)?	Patient safety incidents must be reported to the NRLS. The AT may ask to see anonymised examples of incidents that have been reported.	Our error log allows direct submission to the NRLS.
	Do you report patient safety incidents using the NPSA defined levels of harm?	Patient safety incidents must be reported using the NPSA defined levels of harm (ie near miss, no harm, low, moderate, severe and death). See NPSA website	This is integrated as part of our near miss and error log.

		for explanation of how to categorise risk of harm.	
	Do you have arrangements in place to only allow appropriate staff to participate in the analysis of critical incidents?	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 AT may discuss with you the types of learning that arises from investigating critical incidents/near misses. If the opportunity arises, the AT may be able to share with you learning from other pharmacies, as well as taking away any learning that you would be willing to share with the AT and other pharmacies.	The HubNet is divided into over 20 distinct user types, which have specific access to specific governance modules. The Superintendent and pharmacists have review permissions of the error log so that a summary can be produced.
Arrangements are in place, including record keeping arrangements, for dealing appropriately and timeously with communications concerning patient safety from the Secretary of State[3] and the NHSCB. ToS - 28(2)(c)(iv)	Do you have records to show that patient safety communications from the Secretary of State and the NPSA have been dealt with?	The AT may ask to see the records of the action taken, to assure themselves that the action was taken timeously (in good time). The AT may also wish to discuss the action taken, to assure itself that appropriate action was taken.	Within the HubNet clinical logs there is a Drug Alert recording system which allows for actionable submissions of MHRA Drug Alerts.
Appropriate waste disposal arrangements for clinical and confidential waste are in place. ToS - 28(2)(c)(vi)	Do you have an appropriate mechanism for the disposal of confidential waste?	The disposal of confidential waste may need a shredder, During a monitoring visit the AT may ask how you dispose of confidential waste.	Within the Governance module the following SOPs are applicable: • Clinical waste management

[3] The Medicines and Healthcare Products Regulatory Agency (MHRA), which is an executive agency of the Department of Health, issues safety advice, warnings, alerts and recalls in respect of medical devices on behalf of the Secretary of State, and also safety advice, warnings, alerts and recalls in respect of medicines on behalf of the Secretary of State and the Minister for Health, Social Services and Public Safety, acting jointly. The Department of Health also, separately, issues other communications concerning patient safety, on behalf of the Secretary of State.

The pharmacy should have appropriate safeguarding procedures for service users. ToS - 28(2)(c)(viii)	Have relevant staff been trained concerning child protection?	The AT may discuss with pharmacists during monitoring visits, the local arrangements for child protection to assess understanding and compliance. The Royal Pharmaceutical Society has guidance[4] for its members, and training is available from CPPE.	Within the Governance module the following SOPs are applicable: • Child protection
	Do you have contact details of local child protection officers?	The AT will supply details and may ask for confirmation that you have these during monitoring visits.	This can be found within the Contact Book.
	Have relevant staff been trained on the protection procedures for vulnerable adults?	Training may be obtained from a number of sources, including from CPPE and the AT.	See above.
Monitoring arrangements in respect of compliance with the Health and Safety at Work etc. Act 1974 are in place ToS - 28(2)(c)(ix)	When did you last carry out a Health and Safety risk assessment and Fire Risk Assessment?	The enforcement of HASAWA is the responsibility of the Health and Safety Executive/Local Authority, and therefore the AT does not monitor compliance, but may wish to discuss your monitoring arrangements during the visit. Don't forget, the Health and Safety Executive website provides valuable information to help you comply with your obligations.	This is dealt with by the Local Authority. However, the contact book does list the person responsible for Health and Safety.

[4] http://www.rpharms.com/support-tools/protecting-children-and-young-people.asp (members only)

Clinical effectiveness programme A clinical effectiveness programme is in place, 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. ToS – 28(2)(d)	Do you have a clinical effectiveness programme in place which includes having up to date reference sources, such as BNF and Drug Tariff?	The requirement to provide advice in respect of a repeatable prescription is included in essential service 2, and will be assessed in that section of the CPAF. Similarly the provision of advice for persons caring for themselves or their families is covered in essential service 4 and is assessed in that section. Note: Clinical effectiveness systems should also be designed to improve concordance and to reduce wastage. The AT may discuss your clinical effectiveness programme during the monitoring visit to see how you seek to improve concordance and decrease wastage.	Within the Governance module the following SOPs are applicable: • Repeat Dispensing
	Do your staff know how to use the above reference sources?	When supporting self care under ES6, the staff may need access not only to the medicines sales protocol, but also to other up to date reference books. It is important that they know what information is available, and how to access it, if the pharmacy is going to make good use of skill mix.	Within the Governance module the following SOPs are applicable: • Self care
	Do your staff know when to refer to the pharmacist?	Where members of staff are providing advice to patients and other members of the public, they must be able to make a decision to refer to the pharmacist in appropriate circumstances. The quality assurance of the advice given and the triggers for referrals to the pharmacist may be discussed during a monitoring visit.	Within the Governance module the following SOPs are applicable: • OTC consultations

Staff and staff management programme Arrangements for appropriate induction for staff and locums. ToS – 28(2)(e)(i)	Do you have a written induction programme for members of staff and locums?	The AT may ask to see the programme and any documentation during monitoring visits – see below	Within the Governance module the following SOPs are applicable: • Staff induction
Appropriate training for all staff is in place in respect of any role they are asked to perform. ToS - 28(2)(e)(ii)	Do you have records of training for all members of staff?	The AT may ask to see training records during monitoring visits. The AT may also wish to see that the total hours of staff supporting dispensing activity, who are adequately trained or undergoing training, meets the numerical requirements for the practice payment.	The user has access to all of our training modules and can record additional training in the users training log, this is also backed up by the pharmacists personal requirement for CPD.
The qualifications and references of all staff engaged in providing NHS services are checked. ToS - 28(2)(e)(iii)	Have you checked the qualifications and references of all pharmacists and other members of staff undertaking any activities within the NHS pharmaceutical services?	The AT may ask to see records during monitoring visits, but will not ask to see individual references.	This is a HR requirement.

Arrangements are in place (which must include a written policy) for ensuring that all staff and locums who, arising out of their employment with the pharmacist— • 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 • 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 reasonably 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. • ToS - 28 (2)(e)(vi)	Do you have arrangements in place (in a written policy) to encourage staff, including locums, to raise concerns (commonly known as whistle-blowing)?	The AT may ask to see your written policy on raising concerns during monitoring visits. The Social Partnership Forum has published guidance for the Department of Health to help NHS organisations develop and implement a whistle blowing policy. This includes a template raising concerns policy. You can download the guidance from the NHS Employers website. The General Pharmaceutical Council has also published 'guidance on raising concerns'[5].	This is covered extensively within our HR module. Whistle blowing can be performed using our anonymous complaints tool.

[5] http://www.pharmacyregulation.org/sites/default/files/GPHC%20Guidance%20on%20raising%20concerns.pdf

Information governance programme The pharmacy has an information governance programme, which provides for compliance with approved procedures for information management and security. ToS - 28(2)(f)(i)	Do you have arrangements to comply with the required levels of confidentiality and compliance with the Data Protection Act set out in the Information Governance Toolkit (IGT)?	Approved particulars for the information governance programme were released on 20 March 2012 and require pharmacies to comply with the standards set out in the IGT[6]. The approved particulars will be amended from time to time to ensure that confidential information is given appropriate protection.	This is completed on a separate government website. However we do have Governance Modules covering: • Data protection and confidentiality.
The pharmacy has an information governance programme which provides for submission of an annual self assessment of compliance (to an approved level) with those procedures via approved data submission arrangements which allow the NHSCB to access that assessment. ToS - 28(2)(f)(ii)	Have you submitted your annual assessment of compliance within the last 12 months?	Each financial year (April to March), the standards to be reached will be reviewed, and published. Once the pharmacy has completed its annual IG self assessment, it will be able to respond positively to this question, if it has achieved the level required.	See above.
Premises standards programme The pharmacy has a premises standards programme, which includes 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, ToS – 28(2)(g)(i)	Does the pharmacy have appropriate systems for maintaining cleanliness, designed to minimise the risk of health care acquired infection?	The systems should be proportionate to the risks involved, so for example, if the pharmacy undertakes phlebotomy services, greater safeguards will be needed. The AT may wish to discuss the systems during monitoring visits, particularly if the pharmacy provides services in which there is a higher risk of infection. During monitoring visits, the AT may assess the premises in terms of the infection control measures.	Within the clinical log, there is a cleaning matrix. In addition the Governance module contains the following SOPs: • Hygiene maintenance

[6] https://nww.igt.connectingforhealth.nhs.uk/

The pharmacy has a premises standards programme, which includes 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. ToS – 28(2)(g)(ii)	Do you have arrangements in place to ensure the areas of the pharmacy in which patients receive NHS services comply with the approved particulars?	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.	The Governance module contains the following applicable SOPs: • Maintaining confidentiality
	Is the pharmacy seen by the public to be open for the provision of pharmaceutical services during its core and supplementary opening hours?	This question does not apply to distance selling pharmacies. The premises should have the appearance of being open to members of the public who are outside the premises.	See above.
	Where, for reasons such as security, the doors to the premises are kept locked during any core or supplementary opening hours, is the pharmacy laid out and organized for the following: a) Is a member of staff 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?	This question does not apply to distance selling pharmacies. An arrangement whereby a doorbell is used to summon a response from a member of staff is not sufficient.	See above.

	b) Do staff invite the member of the public to enter the premises if this is necessary to preserve the confidentiality of any discussions, if the facilities needed for the provision of pharmaceutical services are available only inside the premises?	This question does not apply to distance selling pharmacies. ATs may wish to assess compliance with these requirements outside of normal contract monitoring visit hours.	N/A
	Does the area of the premises from which NHS services are provided function 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.	N/A
	Where non healthcare related goods are provided, is there a buffer area between the displays for medicinal products and the non healthcare related items?	The manner in which this is achieved must be practicable and proportionate.	N/A
	Are there appropriate levels of privacy for conversations with patients?	This requirement is in addition to the requirements for those areas used for the provision of advanced services.	N/A
	If you have a confidential consultation area is there a sign stating this?		N/A

	If you have a confidential consultation area or room, does it meet the requirements of the approved particulars?	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.	N/A
	If you have a waiting area or seating available for customer use, are these also appropriate for a healthcare environment?	Any seating provided must be in good working order.	N/A