Essential Service - Clinical governance requirements in the new community pharmacy contractual framework

1. Service description

1.1 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.

1.2 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:

	Component
Resources and processes	
(i) processes for quality improvement	(1) Patient and public involvement (2) Clinical audit (3) Risk management (4) Clinical effectiveness programmes
(ii) staff focus	(5) Staffing and staff management (6) Education, training and continuing professional and personal development
Use of information	(7) Use of information to support clinical governance and health care delivery

1.3 Principles:

1.3.1 Clinical Governance (Continuous Quality Improvement) should be built into all professional services. [organisations are accountable for continually improving the quality of their services and safeguarding high standards]

1.3.2 Clinical Governance is driven by a genuine desire on the part of the contractor and their employees to improve the service that is delivered to patients. [creating an environment in which excellence in clinical care will flourish]

1.3.3 The development of clinical governance of community pharmacy services is supported and encouraged by Primary Care Organisations (PCOs). The providers of community pharmacy services engage in PCO clinical governance programmes. [creating an environment in which excellence in clinical care will flourish].

2. Framework

2.1 Patient and public involvement

2.1.1 The pharmacy should produce and display a practice leaflet

2.1.2 The pharmacy should notify its patients of the NHS services which are being provided by the contractor. This information may be included in the practice leaflet, displayed as a notice in the pharmacy or using an alternative method.

2.1.3 The pharmacy should undertake a patient satisfaction survey annually (based on a national template). The minimum sample size of returned surveys varies in line with dispensing volume as described in the table below.

Average monthly script volume	Minimum number of returned surveys
0 – 2000 items	50
2001 – 4000 items	75
4001 – 6000 items	100
6001 – 8000 items	125
8001 items upwards	150

The pharmacy should review survey results and consider changes which could improve service provision. The pharmacy will share with the PCO the area where the survey identified the greatest potential for improvement and the action being taken to improve performance, along with the areas in which the pharmacy is performing strongly.

2.1.4 Medicines owed to patients or out of stock should be monitored. Patients who cannot be supplied the complete prescription when it is first presented should be issued a written note detailing any medicine owed including the quantity outstanding. The patient should be informed when the medicine is expected to be available and a record of the owing should be made in the patient's medication record.

2.1.5 A complaints system should be in place. The pharmacy should review complaints received, and, as well as taking appropriate action on individual complaints, consider more general changes which could improve service provision.

2.1.6 The pharmacy should co-operate with local Patient & Public Involvement Forum visits and give consideration to any report of such visits and identify and take appropriate action.

2.1.7 The pharmacy should co-operate with PCO and other appropriate external bodies, e.g. CHAI, Local Authority Overview and Scrutiny Committees, on monitoring and auditing of pharmacy services, by authorised persons.

2.1.8 The pharmacy should act on the Disability Discrimination Act 1995 duty to make 'reasonable adjustments' to the physical features of premises.

2.2 Clinical audit

2.2.1 Pharmacists and their staff should participate in clinical audit – at least one practice based audit and, one PCO determined multidisciplinary audit (to aid the development of team working) each year. The PCO must give reasonable notice to allow the pharmacist to leave the premises to participate in any local meetings relating to the multidisciplinary audit. Both audits must have a clear outcome, which will assist with developing patient care. The two audits should be capable of being completed within 5 days of pharmacist time.

2.3 Risk management

2.3.1 Procedures are in place to ensure that all stock is procured and handled in a way that maintains its integrity.

2.3.2 All equipment used in the provision of pharmaceutical services is maintained appropriately.

2.3.3 Incident reporting system – all pharmacies to maintain logs of patient safety incidents, including all stages of the medication process, i.e. not just dispensing errors. The information recorded in the log will populate the mandatory fields in the National Patient Safety Agency's (NPSA) National Reporting and Learning System (NRLS) reporting form. Incidents (with the focus initially on serious ones) will be reported anonymously via NRLS to the NPSA (this may be directly from the pharmacy or via a Head Office system etc.). NPSA are exploring how a copy can automatically be sent anonymously

to the pharmacy's host PCO. Where an appropriate environment and relationship between community pharmacy contractors and PCOs exist, such that community pharmacy contractors are already content to report direct to the PCO, this should continue. Key characteristics of the system will be:

- Non-punitive – PCOs should not link financial incentive payment or non-payment to reporting.
- Confidential.
- Seeks to provide information on patient safety incidents, i.e. not just dispensing errors.
- Open disclosure – telling patients when something goes wrong (includes apologising and an explanation of what will be done to prevent re-occurrence)

In the future (with the agreement of the key stakeholders), when a mature and trusting relationship has developed between PCOs and pharmacy contractors and the necessary IT capability is in place, a transition towards full local, identifiable reporting will take place.

2.3.4 Analysis of critical incidents by the whole pharmacy team to inform individual and organisational learning. Proactive consideration and prevention of potential risks.

2.3.5 Pharmacists should be competent in risk management, including the application of Root Cause Analysis.

2.3.6 Pharmacies should be able to demonstrate evidence of recording, reporting, monitoring, analysing and learning from patient safety incidents.

2.3.7 Standard operating procedures (SoPs) – these should cover all the areas specified by RPSGB as a minimum (this covers the handling of a prescription from receipt to handing to a patient/carer). SoPs should also be produced to cover advanced and enhanced services.

2.3.8 Suitable waste disposal systems for any clinical and confidential waste should be in place.

2.3.9 An identifiable clinical governance lead should exist for each pharmacy. This may not need to be a pharmacist; it could be another member of the pharmacy team. PCOs could request the attendance of one member of staff per pharmacy to attend local clinical governance training each year. The PCO would be liable for paying all training costs.

2.3.10 Health and Safety legislation is complied with in order to reduce the risk of harm to pharmacy staff and the public.

2.3.11 Pharmacy contractors and their staff should comply with local and national guidance relating to child protection procedures. (DH to advise what requirements are anticipated).

2.4 Clinical effectiveness programmes

2.4.1 Systems are in place to ensure appropriate self-care advice is given to patients, e.g. use of protocols/standard algorithms, SoPs.

2.4.2 Through the management and dispensing of repeatable NHS prescriptions for medicines or appliances, in partnership with the patient and the prescriber and the medicines use review service, in particular, pharmacies will contribute to improving the clinical effectiveness of prescribing.

2.5 Staffing and staff management

2.5.1 All staff and locums receive appropriate induction on entering employment, e.g. confidentiality procedures, health and safety issues and security.

2.5.2 All staff are trained or undergoing training appropriate to their role.

2.5.3 The qualifications of all staff providing NHS services are checked and references are taken. [For professional staff this requirement will in part be supported by the introduction of PCO main and in particular, supplementary lists; qualifications etc will be checked prior to entry to a PCO list. These lists may also be used to check a health professional's legitimate requirement to have access to the NHS Care Record Service.]

2.5.4 Contractors should identify and support the development needs of staff providing NHS services.

2.5.4 The main and supplementary pharmaceutical lists, when introduced, will provide a basis for addressing poor performance. Pharmacy contractors and their staff would be expected to co-operate with local poor performance arrangements.

2.6 Education, training and continuing professional and personal development

2.6.1 Pharmacists are able to demonstrate a commitment to continuing professional development (CPD), via a CPD record. This requirement will be rolled out in line with the national RPSGB scheme.

2.6.2 Any necessary accreditation is achieved prior to provision of advanced or enhanced services.

2.7 Use of information to support clinical governance and health care delivery

2.7.1 Pharmacy staff have access to up to date reference sources, such as the BNF and Drug Tariff, and, with appropriate IT links, electronic reference sources.

2.7.2 Contractors and employees need to comply with legal obligations on data protection and confidentiality. This includes the Data Protection Act 1998, Human Rights Act 1998 and common law of confidentiality.

2.7.3 Contractors and employees must conform to the NHS Code of Practice on Confidentiality and contractors must have systems and policies in place to support this, including ensuring staff are appropriately trained.

2.7.4 Employee contracts must include a duty of confidence as a specific requirement linked to disciplinary procedures.

2.7.5 Appropriate patient records are maintained and utilised to improve patient care. Over and above the basic recording of medication supplied, pharmacists will be encouraged to make records of interventions they have made and advice they have given. The need to make such a record is determined by the pharmacist's professional judgement.

2.7.6 Public access to information on how to obtain medicines urgently – pharmacy contractors should ensure that their PCO and NHS Direct are aware of the pharmacy's actual working hours, in order that they can provide appropriate information to members of the public.

2.7.7 Pharmacy contractors display their opening times prominently. In addition and wherever practicable, when the pharmacy is shut, opening times are legible from outside the pharmacy.