South Staffordshire Commissioning Standards for Medicines.

Introduction

The provision of medicines, dressings and appliances is an integral part of healthcare services, and whilst there is no single standard definition as to what constitutes a safe and effective service it is incumbent on service providers to meet a range of standards.

This document sets out the standards expected of all relevant service providers who provide services under contract to South Staffordshire Clinical Commissioning Groups either directly or through associate commissioner arrangements.

The purpose is to that Providers are aware of, and meet the expectations of Commissioners, and for Commissioners in turn to be assured that services involving medicines are fit for purpose and meet the needs of patients.

It is the responsibility of the Provider to ensure that all relevant clinicians are aware of and abide by the standards agreed.

1) National Standards
    a) Care Quality Commission

Essential Standards for Quality and Safety- Outcome 9

Outcome 9 encompasses Regulation 13 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010.

The Provider is required to ensure that this essential standard is complied with at all times. Any concerns relating to a failure to meet this standard or incidents that might materially or potentially indicate a breach are to be reported to the commissioner at the earliest opportunity.

In most cases this will be the next Clinical Quality Review Meeting(CQRM)

    b) Professional Standards for Hospital Pharmacy Services- Royal Pharmaceutical Society July 2012.

These standards apply to Acute, Mental Health and Community Providers, who provide pharmacy services in hospital settings.

These standards provide a framework of good practice and quality improvement that providers are encouraged to adopt. Ultimately the commissioner requires the

standards to be met and the Provider must use their own judgement as to whether they demonstrate this within the proscribed framework or by alternative means.

All relevant providers will be required have undertaken a self- assessment of their services against the standards within this document, and produce an action plan and reporting process to assure delivery.

Providers are required to submit a summary of their compliance and action plan at a CQRM, no later than 30th September 2014.

c) Provider organisations are expected to ensure that pharmacy services provided are adequately resourced from within contract values to deliver a safe and efficient service.

2) Local Standards

2.1 Prescribing in accordance with agreed formularies and guidelines

2.1.1 Provider clinicians will prescribe in accordance with the joint prescribing formulary as published on the hosting CCG web site which includes refraining from prescribing those drugs specifically excluded.
http://www.sesandspccg.nhs.uk/medicines-management

2.1.2 Provider clinicians will not ask GPs to prescribe drugs that are not included in the joint prescribing formulary nor request GPs to prescribe drugs designated as "specialist only" in the formulary.

2.1.3 The Provider will support the Joint Formulary processes through attendance at relevant meetings and use of standard documentation as well as upholding internal Trust processes.

2.1.4 The Provider will ensure that all clinicians are aware of the formulary, how to access and use it, as well as the process for exceptional cases.

2.1.5 Provider clinicians will not request GPs to prescribe drugs for use outside of their licensed indications, unless there is established practice or a substantial body of evidence to support it.

2.1.6 Provider clinicians will not request GPs to prescribe unlicensed drugs, defined as drugs that have not been granted a marketing authorisation in the EU.

2.1.7 The prescribing of " special" formulations should only be considered in cases where a proprietary alternative is not available. If a GP is to be requested to prescribe a "special" the provider clinician will ensure the GP is aware that the requested formulation is unlicensed.

2.1.8 The Provider will at all times refer to drugs by their generic name, other than in situations where it is clinically inappropriate to do so due to bio-inequivalence or in

situations where a particular brand is required. In such situations the reason for specifying a brand must be stated.

2.1.9 The Provider will ensure that whenever possible and appropriate, clinicians recommend a class of drug as opposed to a specific drug. E.g PPI, statin etc.

2.1.10 The Provider will support any national or locally agreed prescribing initiative to improve the quality or cost-effectiveness of prescribing.

2.1.11 The Provider will at all times act in accordance with local commissioning policies which will be published on or linked to the commissioners website

2.1.12 The Provider will at all times act in accordance with national and regional commissioning arrangements. This means that the provider will, from April 2013,be accountable to the relevant appropriate commissioner for each element of service provision. The local CCG commissioner will not underwrite any losses incurred by the provider for failing to act on changes in commissioning arrangements published nationally. This will include any services which might become the responsibility of NHS England as Prescribed Specialised Services, or the responsibility of the Local Authority and Public Health England.

2.1.13 In situations where Providers wish to provide services and products in accordance with a “service specific” formulary other than the Joint Formulary, which may be the case for specific therapeutic areas, e.g woundcare,, continence, sexual health etc. The Provider will seek and obtain approval from the commissioner for each formulary proposed. Once approved, these formularies will also be published on the CCG medicines management website to facilitate health economy engagement. Provider organisations will at all times be responsible for ensuring that formularies are published in accordance with expectations under the *Innovation, Health and Wealth Agenda.*

2.2 Essential Shared care Agreements(ESCA’s and Rationale for Initiation, Continuation and Discontinuation (RICaDs)

Shared care agreements are documents used in some situations where a specialist has initiated treatment and continues to review the patient, but the patients GP has agreed to prescribe the medication. The purpose of the document is to ensure that there is absolute clarity around the obligations of the GP and specialist in terms of monitoring. In most cases the monitoring responsibility will rest with the specialist, the document is to provide assurance to both parties that the care of the patient is being adequately monitored to avoid potential harm from the treatment.

A RICaD is used to inform the GP of the rationale for the specialist choosing a particular drug approach. These documents are used when the patient may not necessarily be followed up in specialist care, and the specialist is discharging the patient back to GP care.

The purpose of the RICaD is to provide the GP with assurance that any qualifying criteria for use of the drug have been met, and that it is appropriate for him/her to take on this responsibility.

The need for an ESCA or RICaD will be established at the Area Prescribing Group. This group will also be responsible for approving the documents produced, and publishing same on the medicines management pages of the CCG website.

2.2.1 When the need for an ESCA is established, this should be drawn-up/adapted by the clinical specialist and submitted to the Area Prescribing Group for approval/ratification

2.2.2 When the need for a RICad is established, clinical specialists should support the production and this will also be submitted to the Area Prescribing Group.

2.2.3 When either an ESCA or RICaD is approved, Provider clinicians are expected to use, or make reference to it when communicating with GPs.

2.2.4 In all cases, Providers should confirm the willingness of the GP to prescribe before assuming that prescribing responsibility has transferred.

2.2.5 A general practitioner has the right to refuse to accept prescribing responsibility if he or she does not feel they have the competence and confidence to take on this responsibility. In such cases the prescribing responsibility will remain with the specialist. In the event that the drug is not excluded from PbR tariff and the provider wishes to recover the costs from the commissioner, they should do so in writing by contacting the relevant clinical commissioning group pharmaceutical adviser.

2.3 Managed Entry of New Drugs and NICE Implementation

South Staffordshire CCGs are committed to meeting their statutory obligations in relation to funding NICE technology appraisals. NICE TA publications are discussed at the Area Prescribing Group, where any process requirements are agreed, along with an agreement to update the joint formulary in accordance with *Innovation, Health & Wealth* requirements. NICE technologies will not normally be available prior to publication of final guidance.

2.3.1 Provider clinicians must not prescribe new or high-cost drugs unless the use has been agreed a) for formulary inclusion or b) via an Individual funding request approval or c) by NICE as part of a technology appraisal. NICE recommendations on the use of drugs, other than in a technology appraisal are discretionary and usage will need to be agreed with the commissioner through the formulary process.

2.3.2 New High-cost drugs or new indications for existing drugs will automatically be considered as low-priority for investment in-year. These drugs will not be routinely available until such a time as their use is commissioned.

2.3.2 In some cases, NICE approval will be subject to the application of a “patient access scheme” In such cases it is the responsibility of the provider to secure discounts and rebates and to invoice the commissioner at a rate net of any rebate or discount.

2.3.4 The provider is responsible for ensuring that any patient receiving a NICE approved treatment meets all the qualifying criteria, both for initiation and continuation of treatment

where these are stated. The Commissioner will seek to recover costs if subsequent evidence identifies use outside of NICE TA guidance.

2.3.5 The Provider will be responsible for maintaining adequate records for demonstrating NICE compliance, which will be made available to the commissioner on request, subject to an agreed period of notice.

2.4 PbR Excluded Drugs

Drugs excluded from PbR are published by the Department of Health, this list is considered exhaustive and all other drugs are deemed to be included within PbR tariff unless specifically agreed through the contracting process.

2.4.1 Not all excluded drugs are however routinely commissioned and Providers must be assured that drugs are commissioned before use. Any invoices for PbR excluded drugs will be rejected if the drugs are not commissioned.

2.4.2 Whilst the costs of commissioned PbR excluded drugs are legitimately chargeable, it is the responsibility of the provider to confirm the commissioning arrangements with the responsible commissioner (see 2.1.12).

2.4.3 The Provider will at all times be responsible for invoicing the correct commissioner for drugs excluded from PbR.

2.4.4 The provider is expected to invoice the commissioner for PbR excluded drugs at cost plus VAT other than in respect of drugs that are supplied through “Homecare” arrangements which are zero rated for VAT purposes. No oncost or surcharges should be added unless specifically agreed with the commissioner.

2.5 Individual Funding Requests (IFRs)

South Staffordshire CCGs operate a policy for the management of Individual funding requests which is available on the website. http://www.sesandspccg.nhs.uk/individual-funding-requests-ifr

2.5.1 Such requests will only be made on the basis of exceptionality as defined within the policy.

2.5.2 The Provider is responsible for ensuring that exceptional funding requests are made in the correct format and submitted to the correct place (IFR team of the responsible commissioner)

2.5.3 The provider is responsible for ensuring any IFR application form is complete, any incomplete forms will be rejected.

2.5.4 Any completed IFR application forms received from Provider clinicians are deemed to have been submitted on behalf of the Provider. Providers may therefore wish to consider internal review arrangements.

2.6 Medicines Bought into Hospital

2.6.1 Providers should provide a medicines reconciliation service on admission in accordance with NICE/NPSA recommendations other than in situations where the admission is of insufficient time to allow this.

2.6.2 The provider should have systems and processes in place to maximise the appropriate use of " patients own medicines". These procedures should ensure that there is no inappropriate destruction of such medicines.

2.6.3 The Provider will operate a policy of supporting self-administration of medication wherever possible and safe to do so in order to maintain independence.

2.7 Medicines Supplied By Hospitals

2.7.1 The Provider will ensure that all medication is reviewed prior to discharge and any necessary changes made.

2.7.2 Discharge summaries/letters should indicate medications that have been initiated and require continuing in primary care, and also a duration for any time-limited interventions. Discontinued medications should also be reported the patients GP to ensure that these are not re-started by the GP inappropriately.

2.7.3 When a patient is discharged from hospital and ongoing medication is needed, the Provider will, at it's own cost, ensure that the patient is discharged with no less than 14 days supply of medication.

2.7.4 The provider will provide medication in the manufacturers original packs whenever possible ensuring that the patient leaflet is available to the patient for reference.

2.7.4 Patients attending "day-clinics" for surgery etc, will be provided with sufficient dressings, antibiotics, or analgesia to meet their post-operative needs by the provider at their own cost.

2.7.5 Patients who attend out-patient clinics who do not require medicines immediately will be advised to obtain a prescription from their GP, (unless provision is made within contract or the medication is designated as specialist only). The clinic must advise the patient that they will write to the patients GP advising on the required medication, and that the need is not considered urgent. The clinic must then provide timely, complete and legible information to the GP practice.

2.7.6 Under no circumstances should a provider issue to the patient a "note" or other handwritten communication to request a prescription from a GP.

2.7.7 If the specialist considers that the medication need is more urgent and can't reasonably wait for the time needed for the GP to receive the letter and generate the prescription, the Provider will supply the necessary medication at the cost of the Provider. Original pack dispensing rules apply, or a full course in the case of antibiotics etc. The provider must ensure that adequate information reaches the GP before further supplies are likely to be requested.

2.7.8 Drugs that are designated as "specialist only" will remain the responsibility of the Provider to prescribe and where appropriate, supply. GPs should not be asked to prescribe

these drugs, as set out in 2.1.2. However, it may be appropriate to share the information as to what medication the patient is receiving from the specialist for safety purposes. In communicating this information the Provider will ensure that there is clarity as to where prescribing responsibility lies.

2.7.9 The provider is responsible for ensuring that patients receive sufficient advice and information relating to medicines prescribed in hospital, to ensure safe and effective use.

2.8 Medicines Supplied via Homecare Providers

The provision of medicine via homecare companies is now commonplace in England. Such arrangements are accepted as providing cost benefits to the NHS by moving drugs from being subject to standard rates of VAT to being zero rated. These arrangements also provide more convenient access to drugs by patients.

The contracts are however generally between the Acute Trust provider and the “homecare” company, and the commissioner therefore wishes to assure compliance with best practice by including the following clauses, which relate solely to those areas of care for which the CCG commissioner is responsible.:-

2.8.1 Procurement of Homecare services by a provider must be undertaken in accordance with guidance published by the Commercial Medicines Unit (CMU) at the Department of Health.

2.8.2 The Provider should ensure robust governance relating to third party (homecare) provision, including reconciliation of invoices against orders etc.

2.8.3 The Provider will ensure that the commissioner is aware of any planned changes in homecare provision arrangements.

2.8.4 The Provider will ensure that the same level of patient level detail can be available for patients receiving drugs via homecare services as for patients receiving drugs directly from the hospital.

2.8.5 The Provider should ensure that drugs supplied through “homecare” companies are recorded in such a way as to facilitate national data collection arrangements for usage of such drugs.

2.9 Clinical Trials

The commissioner recognises the value of clinical trials both in terms of advancing therapeutic knowledge but also the potential for cost-saving as “trial” drugs will generally be funded by the manufacturer.

2.9.1 Patients recruited to participate in clinical trials by the Provider must be given a full explanation of the trial and its duration. Patients should also be advised that the treatment is not routinely available on the NHS and that the commissioner makes no commitment to fund the treatment at the end of the trial irrespective of any significant benefit gained.

2.9.2 In cases where treatment cannot be stopped at the end of a trial, the provider must seek agreement from the commissioner as to how this will be managed. The commissioner will not undertake to fund treatment in this scenario without prior agreement.

2.9.3 Providers participating in clinical trials are required to inform the commissioner of any financial risk that might be hidden as a result of an ongoing trial. For example, if the contract value for drugs is set artificially low as a result of a cohort of patients that would otherwise have their treatment funded , due to them receiving free drug as part of a trial, and at the end of the trial the NHS costs will be incurred and a funding gap exposed.

2.10 Private Practice

2.10.1 The commissioner will not fund drugs that may have been initiated on a privately funded basis, unless they are subsequently commissioned for a cohort of patients. In circumstances where a patient opts out of private care or can no longer afford it, they will be entitled to receive the same level of NHS care as other patients.

2.10.2 Clinicians providing private care have some obligation to ensure that the patient is in a position to fund the complete course of treatment.

2.11 Governance and Engagement

2.11.1 Providers will engage in the medicines agenda with commissioners through representation and participation in the Area Prescribing Group and any relevant sub-groups.

2.11.2 Providers will support delivery of assurance and compliance with Regulations relating to controlled drugs by publishing the name of an Accountable Officer for Controlled Drugs, where required to do so, the submission of occurrence reports, and representation at the local intelligence network for controlled drugs. Whilst lead responsibility for this agenda now rests with NHS- England, local commissioners will expect compliance with all relevant controlled drugs Regulations, in support of patient safety and quality.

2.11.3 Each Provider will produce and maintain a suite of policies and procedures relating to medicines use which might reasonably be expected of such a provider to demonstrate compliance with national and local standards.

2.11.4 Providers will upon request engage is discussions relating to gainsharing and commissioning of more efficient ways of working to deliver the QiPP agenda.

2.11.5 Providers will at all times operate a culture of transparency in any dealings with the commercial sector. The provider will inform the commissioner of any agreements relating to sponsorship of posts or similar agreements that might impact on prescribing in primary care or otherwise influence costs to the commissioner.