A Summary of Pharmacy Support required to deliver Medicines Optimisation in Primary Care based and Community Health Services: A guide for Organisational Boards and Service Commissioners

A briefing document for service commissioners and Board members of standalone primary healthcare service provider organisations which summarises the requirement to have adequate pharmaceutical advice, highlights the risks to the organisation of failing to do so and explores the options open to organisations of how that support may be delivered.

Executive Summary – points to consider by organisations providing Primary and Community Health services

Has your organisation got formal access to strategic knowledge and understanding of pharmacy services and the legislation associated with medicines use, from a senior pharmacist with experience in the settings where you deliver care?

What evidence does the board receive that medicines are used safely across the whole organisation?

How will your organisation demonstrate to the CQC that all aspects of medicines optimisation meet the requirements to be safe, effective, caring, responsive and well-led? If your organisation provides services in Health and Justice settings do they meet Her Majesty's Inspectorate of Prisons Expectations?

If an incident concerning medicines occurs, do you have the pharmaceutical expertise available to fully investigate this?

Is the local mechanism for the commissioning of medicines optimisation services fully understood?

If your organisation is commissioned to provide more complex ‘Care Closer to Home’, do service managers have the pharmaceutical expertise available to them to fully consider the implications of all aspects of medicine use?

How will your organisation develop and implement Patient Group Directions (PGDs), have you assurance that they meet all the legal requirements?

Is your organisation compliant with medicines-related NICE guidance?

Have all medicines-related Patient Safety Alerts including previous NPSA alerts been implemented within the organisation?

How does your organisation ensure it is compliant with CD regulations?

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Background
Delivering primary care and community health services is a multidisciplinary aspect of healthcare with a whole range of professionals contributing to the care of individual patients. Many patients are seen in their own homes, or closer to home, by a variety of community and acute services from both the health and social care sectors. Increasing numbers of complex procedures, treatments and interventions, plus changes in the type of patients and conditions, are now taking place in primary care or community settings, including in community hospitals and clinics, the patient’s own home and secure environments such as prisons, police custody suites and immigration removal centres.

Medicines are the most common treatment intervention in the NHS and almost all services involve their use. Risks as well as benefits are associated with the use of medicines as evidenced by for example the number of Patient Safety Alerts that focus on medicines; in addition at least 6% of emergency admissions are a direct result of problems with medicines. All NHS legislation forms part of criminal law, therefore it is advisable that organisations delivering services involving medicines employ, or have access to a senior pharmacist, with relevant experience, who can translate this into safe and legal practice for the benefit of the organisation and for the protection of employees.

Legal requirements, National guidance and Standards
Organisations must demonstrate to the CQC that all aspects of medicines optimisation meet the requirements to be safe, effective, caring, responsive and well-led. This requires adequate pharmaceutical advice to achieve compliance.

In addition organisations providing services in Health and Justice settings need to meet Her Majesty’s Inspectorate of Prisons Expectations. All organisations that use medicines must:

- comply with the legal framework that governs medicines, including the 1968 Medicines Act, the Misuse of Drugs Act 1971 and its associated Regulations, the Health and Safety at Work Act, the Control of Substances Hazardous to Health Regulations, the Disposal of Hazardous Waste Regulations and the Health Act 2006
- Comply with guidance from the National Institute for Clinical Excellence (NICE) and respond to NHS England Patient Safety Alerts, MHRA safety warnings etc.
- provide evidence of appropriate medicines optimisation to the Care Quality Commission (CQC)
- ensure that its legal obligations are met, e.g. Accountable Officer for Controlled Drugs, PGDs and waste management

Risks in medicines use
The strategic direction of the NHS includes provision of patient centred services provided closer to the patient’s home. As stated above, risks as well as benefits are associated with the use of medicines. The impact of moving a service to a ‘new’ community based setting can result in ‘different’ risks and unforeseen problems that need to be overcome. Advice will be needed from an experienced pharmacist to assure service quality and the safe, effective management of medicines, ideally starting at the business case stage, and following introduction of any new/redesigned service. Incidents reported to the National Reporting and Learning System (NRLS) have included:

- Problems associated with resuscitation in emergency situations created by moving a service to a new environment
- Vaccine administration errors
- Death from the wrong dose of insulin
- Amputation from lack of availability of clindamycin IV for home treatment due to inadequate supply chain.

In secure environment settings there are additional risks with the abuse, diversion and trading of medicines, barriers to patient’s open access to healthcare services resulting in complex arrangements for medicines handling and governance. Provision of safe medicines use in these environments is very challenging and requires the oversight by robust pharmaceutical leadership.

Medicines are used by various healthcare professionals within the standards and guidance issued by their individual professional bodies. Each practitioner is responsible for their own practice but a senior, experienced pharmacist has the competencies needed to ensure the organisation has appropriate clinical governance oversight and evidence to show that all staff in the organisation handling medicines are following legislation, policies and guidance.

Medicines Optimisation Requirements of a Primary Care or Community Health Services Organisation
Organisations must ensure they have adequate pharmaceutical resources to provide appropriate professional advice as follows:

**Strategic Support**

- An accountable person, through delegation from the Chief Executive, for compliance with legislation and NHS directives relating to the organisation’s prescribing and medicines optimisation services.
- An identified resource for professional leadership and the development and implementation of a medicines optimisation strategy for the organisation. This medicines optimisation strategy will support the organisation’s continuous quality improvement and safety programme related to the use of medicines. It will ensure that medicines safety is embedded into each of the organisation’s services. In addition it will make the organisation aware of new national developments that will impact on the organisation.
- An Accountable Officer for Controlled Drugs (NB This will be needed if/when the organisation becomes a ‘designated body’ under the Health Act Regulations SI 2006 No. 3148).
Governance Structures

- An appropriate internal governance route for approval of medicine-related policies and procedures, incident reports, risk assessments and assessment of compliance to national standards and directives.
- A governance route for approval of non-medical prescribing applications and for Patient Group Directions. (Note 1: A doctor or dentist, with accountability to the provider, is required to support the development of PGDs along with the pharmacist and the clinicians using the PGD. Note 2: at the time of writing PGDs for NHS-commissioned services could only be authorised by certain legal bodies see NICE guidance Link).
- Representation on the local health economy Medicines Optimisation group (or equivalent) to maintain relationships with other providers and promote consistent policies across the local health economy e.g. managed entry of new drugs, antibiotic prescribing.

Pharmaceutical support

Access to suitably experienced pharmacists and pharmacy technicians who are responsible for

- Identifying medicines optimisation/pharmacy requirements for new services, service developments or as part of service redesign e.g. home IV services. This could include advice on the content of a contract with another pharmacy provider.
- Providing pharmaceutical advice to resolve medicines optimisation issues/queries in a timely fashion.
- Providing pharmaceutical support for investigation and management of medicine-related incidents and risk management within the organisation.
- Development and implementation of medicine-related policies and procedures to support clinical teams with the safe and effective use of medicines.
- Advising on the implementation of medicine-related NHS England Patient Safety Alerts, NICE guidance and provision of evidence of compliance.
- Supporting and monitoring medical and non-medical prescribing to ensure high quality and cost-effective prescribing and supporting the development of Patient Group Directions (PGDs) or protocols to support the safe supply and administration of medicines within the organisation.
- Development and provision of training to ensure the appropriate level of medicines optimisation knowledge and skills within the workforce to deliver safe and appropriate care.
- Ensuring that medicines are procured and delivered in a safe and cost-effective manner.
- Providing or organising a quality medicines optimisation service for ‘bedded services’ and related services e.g. admissions avoidance teams, that includes medicine review and reconciliation on admission and discharge planning.
- Evidencing that the organisation can demonstrate to the CQC that all aspects of medicines optimisation meet the requirements to be safe, effective, caring, responsive and well-led.
Pharmacy service options in organisations

It is acknowledged that pharmacy support to organisations may be delivered in a number of ways. The following four options are currently the most common ways pharmaceutical support is delivered to standalone organisations. The strengths and weaknesses of the different options are considered along with some points to consider.

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<tr>
<th>Type of arrangement</th>
<th>Strengths</th>
<th>Weaknesses</th>
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| 1. **Option 1**  
Stand alone organisation directly employs its own pharmacy staff for all professional advice and all clinical input to bedded units. This team manages the contract for supply of medicines etc. | • Ability to influence organisation at strategic level  
• High visibility of the pharmacy team and direct communication with the ‘end user’  
• Alignment of objectives with the organisation’s objectives  
• Easier to embed medicines optimisation into the organisation’s governance structures and accountability arrangements  
• Easier to identify pharmacy resource required for services, particularly as organisation develops to deliver more complex services  
• Directly employed staff ensures better continuity of service once in post | • Internal pharmacy team may become isolated from wider medicines optimisation issues  
• Internal pharmacy team may not have all required skill mix e.g. clinical skills, ePACT analysis  
• Recruiting problems may result in gaps in service |

Points to consider:

a) This may not be the preferred model where the clinical screening of prescriptions would be separated from dispensing. Governance arrangements and clear lines of accountability would need to be clearly documented in contracts if this model was used.

b) Size of the organisation - small organisations may not be able to sustain a critical mass of pharmacy resource and may need to be shared with another organisation to obtain the skill mix/resource required. This may also impact on recruitment and retention.

c) Communication links - it is important that medicine optimisation issues within the organisation are integrated across the whole health economy e.g. membership of local health economy Medicines Optimisation Committee or equivalent.
### 2. Option 2

Organisation employs a senior pharmacist responsible for strategic professional support and managing contracts for all other medicines optimisation support.

- Ability to influence organisation at strategic level
- Use of skill mix from larger pharmacy teams under contract to support clinical services
- Some integration with wider medicines optimisation services
- The senior pharmacist could be professionally isolated
- Contract management is time-consuming. Will require regular revision to react to changes in activity
- Pharmaceutical services under contract may not be able to respond in a timely manner to changes in direction of organisation e.g. supporting new initiatives will require regular revision of contracts to react to changes in activity
- Annual leave and sickness cover may be problematic
- Recruitment problems within the contract provider may result in poor service provision
- Ownership of some issues may be difficult to resolve

### Points to consider:

a) Seniority of directly employed pharmacist – needs to be sufficiently senior to have the ability to provide leadership and influence organisation strategically and be member (or directly report to a member) of senior decision-making groups within the organisation.
b) Cover for leave – the senior support is likely to be one pharmacist, unless a job share is considered, so need to ensure there is adequate cover for leave. This may need to form part of a contract.
c) Succession planning may be difficult.
### Option 3

Organisation has a hybrid of options 1 and 2. For example it employs a senior pharmacist responsible for strategic professional support, and it employs pharmacists / pharmacy technicians to undertake medicines optimisation related audits. The remainder of the medicines optimisation support is obtained via a contract for example the clinical and supply service for the bedded units are both obtained from another organisation.

- Ability to influence organisation at strategic level
- Easier to embed medicines optimisation into the organisation’s governance structures and accountability arrangements
- Opportunity to ‘pick and mix’ pharmacy services delivered by directly employed staff, while outsourcing other aspects of medicines optimisation
- Some integration with wider medicines optimisation services
- Directly employed staff ensures better continuity of service once in post
- Pharmaceutical services under contract may not be able to respond in a timely manner to changes in direction of organisation e.g. supporting new initiatives will require regular revision of contracts to react to changes in activity
- Recruiting problems may results in gaps in service
- May be difficult to get the appropriate skill mix in a small team
- Annual leave and sickness cover may be problematic

### Points to consider:

a) This option may be suitable for smaller organisations, where a whole pharmacy team is not a viable option but the organisation wants to ensure that medicines optimisation is embedded in the organisation.

b) Depending on the size of the team there may still be issues with cover for leave.
### Option 4

Organisation obtains **all** professional advice and clinical support through a **contract** (e.g. with the acute Trust), as well as contract for supply etc.

- Use of skill mix from larger pharmacy teams under contract to support the organisation
- Activity levels can be clearly defined in a contract
- Potential for integration with wider medicine optimisation services
- Large department should mean that recruitment gaps can be covered

- Degree of separation from the ‘end user’
- Contract management is time-consuming. Will require regular revision to react to changes in activity
- Without any pharmaceutical advice within the organisation, the monitoring of the contract will have to be undertaken by another clinical lead
- May be difficult to ensure ownership and senior accountability for medicines optimisation within the organisation
- Difficult to influence organisation at strategic level
- Contract not seen as part of core business by the contract provider
- Even if recruitment gaps are covered the competences of staff providing service may be inappropriate

### Points to consider:

- **a)** Organisation management and governance structures – need to ensure that there are clear lines of accountability for medicines optimisation governance.
- **b)** Contracts – need to ensure that there are robust contracts in place that define roles, responsibilities, and accountability arrangements – (see Contract toolkit [Link](#)) and the resource available to manage and review them.
- **c)** Other clinical leads will need to undertake guideline development, prescribing advice, pharmacy contract management. They will not have the skills of a senior pharmacist.