

NHS England Area Team HM Prisons Medicines Standards

Health and Justice Commissioning

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London Area Team Medicines Standards)

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1 Introduction

The Department of Health requires that providers of NHS services establish, document and maintain an effective system to ensure that medicines are handled in a safe and secure manner.

This standards document covers any organisation or contractor commissioned by NHS England Health and Justice Area Teams to provide healthcare services which include pharmaceutical or medicines management activities such as purchasing, storing, transporting, prescribing, dispensing, administering and disposal of medication.

It defines the standards expected by NHS England as commissioners and is in addition to specific contracts and agreements. Private and NHS Organisations will need to develop local policies and procedures to ensure that medicines are handled safely, securely and in accordance with the legislation, professional standards and best practice guidance that applies to their activities.

Providers are expected to have a formal arrangement in place for access to pharmaceutical advice to support them in achieving these standards – this may be from an employed pharmacist or through an agreement with an organisation or individual. Prescribing advice may only be given by a pharmacy professional or prescriber and will be in line with national and local policies and guidelines. Advice provided by other healthcare professionals e.g. pharmacists, nurse practitioners, nurses, dieticians, physiotherapists and others must be within agreed local guidelines and any recommendations to patients or other clinicians that may affect prescribing should be within these parameters.

Providers are expected to have a formal arrangement in place for the governance arrangements and development of the infrastructure to support safe medicines handling and use within the organisation. This should meet national best practice and include:

- A functioning medicines management committee (MMC) with Terms of Reference and specific accountabilities to a prison/healthcare governance or prison health partnership board. The MMC should include input from a pharmaceutical adviser or supplying pharmacist and other stakeholders such as prison security, clinicians and drug strategy involvement.
- A named lead who operationally is accountable and responsible for the day to day delivery of the governance infrastructure
- An overarching medicines policy or code that describes the principles or basis on which medicines are used and handled within the organisation. This policy should be underpinned and operationalised by formularies, procedures and relevant additional policies.

The Provider is responsible for networking with other providers of pharmaceutical services to prisons, and through this networking, be able to evidence the sharing of best practice.

2 Handling medicines

The commissioner expects providers to meet the standards of the relevant legislation and local and national guidance for the processes of ordering, storing, transport, supply, administration and disposal of medicines, including but not limited to those in the table below.

	Standards
Applicable for the integration of medicines in all care pathways	<ul style="list-style-type: none"> • Medicines Act 1968 • Human Medicines Regulations 2012 • Misuse of Drugs Act 1971 • Misuse of Drugs Regulations 2001 • Misuse of Drugs (Safe Custody) Regulations 1973 • The Health Act 2006 • Health and Social Care Act 2008 • The Equality Act 2010 • European Community Directive 2001/83/EC • Environment Agency T28 – Sorting and Denaturing Controlled Drugs for Disposal • Royal Pharmaceutical Society Medicines, Ethics and Practice • Nursing & Midwifery Council Standards for Medicines Management • Good Practice in prescribing and managing medicines and devices (2013) – Guidance for Doctors • DH Protocol for ordering, storing and handling vaccines • Control of Substances Hazardous to Health (COSHH) Guidance • Current good practice guidance issued by organisations including RPS, GPhC, MHRA, DoH, Home Office, NPSA etc • A Guide to Good Practice in the Management of Controlled Drugs in Primary Care (National Prescribing Centre) • A single competency framework for all prescribers (National Prescribing Centre) • Patient Group Directions (NICE Good Practice Guidance) and subsequent national guidance detailing the development and governance for the use of PGDs available at: http://www.medicinesresources.nhs.uk/en/Communities/NHS/PGDs/About-us/ • The Safe and Secure Handling of Medicines: a team approach (Royal Pharmaceutical Society) • Medicines optimisation: helping patients to make the most of their medicines. Good practice guidance for healthcare professionals in England may 2013 (Royal Pharmaceutical Society)
For On-site Pharmacy service provision or standards for external, subcontracted Pharmaceutical Services	<ul style="list-style-type: none"> • Community Pharmacy Contractual Framework • Standards for pharmacy owners and superintendent pharmacists of retail pharmacy businesses (General Pharmaceutical Council) • Good Dispensing Guidelines (Royal Pharmaceutical Society) • Guidance on the Procurement and Supply of Pharmaceutical Specials (Royal Pharmaceutical Society) • Professional Standards for a Hospital Pharmacy Services (Royal Pharmaceutical Society)
Prison healthcare service specific requirements	<ul style="list-style-type: none"> • PHPQI Indicator 1.3 Medication Safety • Medication In-possession. A guide to improving practice in secure environments (National Prescribing Centre) • A Pharmacy Service for Prisoners (DH) • PSI IDTS 2010/45 • Clinical Management of Drug Dependence in the Adult Prison Setting DH 2006 • Provision of FP10 and FP10[MDA] prescription forms by HM Prison Service for released prisoners • RCGP Safer Prescribing in Prisons 2011 • PHE Management of Persistent Pain in Secure Environments 2013

2.1 Handling medicines – additional points

2.1.1 Purchasing ‘special order’ products

Contractors will consider the cost to the NHS when purchasing ‘special order’ products which are not listed in the Drug Tariff and:

- Advise the prescriber of the cost and discuss alternatives
- Ensure that the quantity prescribed and ordered minimises waste
- Purchase from a supplier offering best value to the NHS. It may be quicker and cheaper to order directly from the manufacturer rather than via a wholesaler / distributor. Information is available from the local CCG Medicines Management team.

2.1.2 Dispensing

- Medication will be supplied on a named patient basis whenever possible, and patients who wish to self-administer their medication will be supported to do so when it can be done safely. Patient specific prescriptions will not be used to top up stock.
- Dispensing will take place via pharmaceutical services following the service specification detailed in the contract. This service specification should be used for on-site and external and sub-contracted pharmaceutical services
- It is envisaged that for **local remand prisons** where offenders are admitted from court that pharmacy dispensing services will be provided from an **on-site pharmacy** unless explicitly stated otherwise in the service specification.
- Secondary dispensing (i.e. the re-packaging) by the provider of medicines dispensed for individual patients or stock medicines is not allowed.
- In order to comply with European Community directive 92/27/EEC on pharmaceutical labelling, and the provision of information to prisoners, the pharmacy will normally be expected to dispense/supply medicines in prisoner packs.
- Where original packs are not clinically appropriate (eg risk of self harm, continuing dose adjustment) providers will make alternative arrangements to ensure prisoners receive information as required by the directive 92/27 EEC.
- Communication systems should be in place to ensure accurate and timely information about an individual prisoner's medication is available to the appropriate professionals responsible for his/her care.

2.1.3 Charging offenders for medication

Providers who supply medication which attracts a charge to offenders will limit this to General Sales List (GSL) and Pharmacy Medicines (supplied under the supervision of a pharmacist) within a homely remedy policy (see 4.6.14) and have written protocols and arrangements in place to:

- Ask patients to sign to confirm that they will pay for these medicines
- Check at the point of supply whether the medicine is appropriate for the patient
- Record in the clinical record when the supply has been made
- Collect payment from those patients via agreed local arrangements

2.1.4 Emergency Medicines and access to Medicines Out of Hours

- In settings where it is recommended that medication is held in case of medical emergency (for example dental surgeries, vaccine clinics) providers will comply with national guidance where available (eg guidance for [dental practices](#), [Resuscitation Guidelines](#)).
- Where medicines are needed out of hours, this need to be met via arrangements with out of hour service providers and external pharmacy providers (including local NHS Trust hospitals for specialist medicines).
- Out of hours access to certain medicines may be made available by the provider using a supply based in the prison but access should be via agreed protocols

and policies with documentation of each supply made from this arrangement in the clinical record.

- There will be procedures in place to ensure safe and secure storage, and regular recorded checks on expiry dates. Staff will be trained in the use of the medication and be aware of the location.
- There will be protocols on the use of the medication and any medicine supplied to the patient for self-administration will be labelled according to the Medicines Act.

2.1.5 Medicines Storage

- Medicines storage should be in line with national guidance and regulatory requirements
- Refrigerators should be used for the sole purpose of medicines storage and be checked regularly underpinned by SOPs that detail the action to take should fridge temperatures deviate from those required.
- Medication storage in prisoner accommodation rests with the prison estate. Consideration should be given to the need for lockable storage for medicines in shared accommodation
- The provider will ensure all medical gases are appropriately stored, and that Control of Substances Hazardous to Health (COSHH) information and advice is accessible in the healthcare centre.

2.1.6 Patient's own drugs

- On admission or transfer an assessment of patient's own medication should be included in the reception screening process or equivalent within 24 hours of admission
- Any medication deemed unsuitable for use should be destroyed as per local policies and procedures and an assessment and re-supply made by the provider in a timescale that avoids omitted and delayed doses.
- The provider should ensure patient consent is obtained should a patient's own medication need to be destroyed.
- On release or transfer from the prison the provider should ensure that discharge planning and transfer process enable continuity of supply/administration of medicines by the patient in the community or by the receiving prison (see section 4.4.1)

2.1.7 Medicines in compliance aids

- Compliance aids should be filled by a pharmaceutical services provider and should
 - allow identification of individual products
 - be fully labelled
 - be assessed as suitable by a suitably trained member of staff.
 - not contain schedule 2 or 3 controlled drugs
 - should be treated as all other patient's own medication in line with local policy.
- Compliance aids should not be filled from medicines already dispensed in individually labelled packs (as this is secondary dispensing) or from healthcare stock unless this activity is completed by an on-site pharmacy and the compliance aid meets the requirements above.
- Patients should be encouraged to self-administer their medication from the compliance aid, where they can do so safely, to ensure that the skills are not lost during their stay.

2.1.8 Illegal drugs

Providers will have in place a procedure for dealing with illegal drugs brought in to their premises by service users or other visitors.

2.2 The Equality Act

- Providers are expected to meet the requirements of [The Equality Act 2010](#) by assessing patients and making appropriate adjustments to their services. Where this involves the provision of medicines compliance aids filled as in 3.1.6 above:
- Patient assessment and the selection of appropriate compliance aids (which include monitored dosage systems, reminder charts, easy open containers and large print labels) is the responsibility of the provider within an agreement with the provider of pharmacy services who dispenses the medicines on behalf of the provider.
- There will be a procedure in place covering the assessment of patients and the provision of compliance aids
- The requirement is to support the patient in managing their own medication. There is no need to provide compliance aids where the patient is not self-medicating.
- The [assessment](#) will be recorded and the provider must be able to justify their decision if required
- The provider must ensure that provision of compliance aids is included in discharge planning and transfer resulting in continuation if these requirements for the patient.
- Stability of the products within the compliance aid will be a factor in the decision.
- Pharmacy service providers will not request additional funding through the provision of 7-day prescriptions but should be within agreed contractual arrangements and costs within in-house and external pharmaceutical service provision.

2.3 Controlled Drugs

The Provider shall ensure it has robust arrangements for the safe and secure use and handling of controlled drugs in line with national regulations and guidance, in particular [NPC report Safe Management and Use of Controlled Drugs in Prison Health in England](#). Whilst recognising that NHS England Area Teams have an appointed CD Accountable Officer (CDAO), the commissioner will seek assurance that national regulations and standards are being adhered to, and requires a copy of the CD Quarterly occurrence report to be provided to the NHS England Area Team CD AO. Additionally the provider will allow the Commissioner and the NHS England Area Team CDAO to access premises to conduct audits, inspections and investigations.

2.3.1 Details of CD Handling

General

- Designated bodies will appoint an Accountable Officer (AO) for Controlled Drugs (CDs) and will notify the NHS England Area Team CDAO and commissioner of any change of post holder.
- Other providers may be requested by the commissioner and/or CDAO to appoint a CD lead who will be expected to act in the same way as an AO.
- It is the legal responsibility of the provider to acquire and evidence to the commissioner and NHS England Area Team CDAO that the necessary [Home Office CD Licences](#) are in place for both possession of CDs and acquiring stock CDs from licensed CD suppliers.
- CDAOs and CD leads will, within the framework of the NHS England CD Local Intelligence Network, share information regarding the management of CDs
- The CDAO is responsible for ensuring that providers have Standard Operating Procedures in place to cover as a minimum:
 - Who has access to CDs
 - Where CDs are stored
 - Security
 - Disposal and destruction
 - Who should be alerted if complications or concerns arise
 - Record keeping including CD Register and record of patient returned CDs

Concerns relating to Controlled Drugs

- Organisations will have procedures in place to ensure that complaints, incidents and concerns relating to Controlled Drugs are brought to the attention of the appropriate CD Accountable Officer (CDAO) and the commissioner. For designated bodies this will be their own CDAO, for others this will be the specified NHS England Area Team CDAO.
- Serious concerns about any element of the management and use of controlled drugs should be reported to the NHS England Area Team CDAO, the police, the Local Intelligence Network, the local Clinical Performance or equivalent group, the commissioner and / or the relevant regulatory body.
- CDAOs and CD leads will provide quarterly reports of their CD occurrences to the NHS England Area Team CDAO with a copy provided to the commissioner.

Destruction

- Providers will obtain the appropriate Environment Agency licences or [exemptions](#) before denaturing CDs
- Destruction of patient returned CDs will be witnessed by an authorised member of staff in line with local procedure
- Destruction of out of date and unwanted stock CDs will be witnessed by one of the groups listed in the regulations, or by someone formally authorised by the AO of the organisation or authorised by the NHS England Area team CDAO. Organisations with an AO will have a procedure detailing the criteria for witnesses. These will be staff who are subject to a professional code of ethics or a CRB check, and who are independent from the day to day handling of CDs. They will be suitably trained.
- Organisations with a CD lead may request authorisation from the NHS England Area Team CDAO for staff who meet the criteria.
- Primary care contractors (other than large pharmacy companies who have their own witnesses) and other providers with no AO may contact the NHS England Area Team CDAO to arrange a visit from an authorised witness.
- Providers who administer CDs will have a procedure in place to cover the arrangements for the disposal of any unused portion of an injection. Where possible there should be a witness to this procedure.

Prescriptions & Requisitions (in general + specific professions or providers):

Prescriptions

- NHS prescriptions including FP10/FP10MDA prescriptions and internal prescriptions provided as part of NHS commissioned services must meet the written or computer generated requirements for CD prescriptions as detailed in the current BNF.
- Providers with an in-house pharmacy, or who have a formal supply arrangement with an external pharmacy, may use an in-house prescription which complies with the legislation.
- For HM Prison prescriptions as these services are commissioned as NHS services CD prescriptions **are not** considered private and thus the usual FP10 and FP10MDA prescriptions can be used for urgent medicines and unplanned discharges **only**.
- FP10 and FP10MDA prescription pads for the purposes above can be accessed via the NHS England Area Team

Requisitions

- Providers, including HM Prisons with an in-house pharmacy, or who have a formal supply arrangement with an external pharmacy, community or otherwise, may use an in-house order which complies with the legislation.
- The requisition must be counter-signed by a Doctor or Pharmacist as required by the Misuse of Drugs Act 1971 and associated guidance.
- In line with regulations for wholesale dealing and Misuse of Drugs Regulations, healthcare providers must source CD stock supplies from a licensed wholesale dealer who has the necessary CD supply licences.

Prison Healthcare specific requirements

- The prison will have procedures in place to ensure that the processes for ordering, prescribing and supplying CDs within the prison comply with the standards applicable to the legislation and in addition meet the requirements of [PSI IDTS 2010/45](#) and Section 21 [A Guide to Good Practice in the Management of Controlled Drugs in Primary Care \(National Prescribing Centre\)](#)
- In all prisons, IDTS programmes are in place. The provider will be required to manage IDTS medicines on all sites where this is included in the healthcare service provider's contract or if formal agreements are in place for the sharing of CD handling tasks with a separate IDTS service provider. This may include the (observed) dispensing of methadone, buprenorphine and other prescribed medication, as well as ordering and stock control and the management of Controlled Drugs in accordance with relevant legislation and prison policy.
- Where other providers deliver services into the prison that include the prescribing or use of stock CDs (Schedule 2-5) the healthcare provider must ensure there is a clear delineation of ownership, accountability and handling of CDs between their organisation and the other provider. For example where the other provider requisitions and supplies CDs the other provider will need the relevant licences and will need to record CD transactions in a separate CD register to the one held by the healthcare provider.
- Healthcare providers in prisons will need to ensure that prisoners receive continuity of their CDs on transfer. To achieve this providers will need to provide to the receiving prison:
 - a copy of the original Schedule 2 or 3 CD prescription showing the handwritten signature of the prescriber is sent to the receiving prison
 - a supply of the CD (if this is not held as stock in the receiving prison) is sent and information on the recent administration history of the CD to the patient.
- The use of FP10/FP10MDA prescriptions for use in un-planned discharges included unplanned court appearances is now authorised across England. Prison healthcare providers should ensure they implement the use of these prescriptions in unplanned release pathways to minimise the risk of omitted or delayed access to CDs by released prisoners.

Prescribing monitoring

- Providers will have procedures in place to monitor inappropriate, unusual or excessive prescribing and report this to the commissioner and NHS England Area Team CDAO.
- The NHS England Area Team CDAO and commissioner will monitor inappropriate, unusual or excessive CD prescribing by prescribers (including non-practice prescribers, non-medical prescribers and private prescribers). Providers will respond promptly to requests for information or clarification.

Self-assessment

The NHS England Area Team CD Accountable Officer will periodically require those on the Area Team Performer's List to return a self-assessment and declaration. Prescribers and providers will respond promptly.

Inspection

The NHS England Area Team CD Accountable Officer may make periodic inspections of those on the Area Team's Performer's list to check physical arrangements for storage, record keeping and management of CDs. Providers will allow access on request.

3 Prescribing

The commissioner expects providers to meet the standards of the relevant legislation and local and national guidance for prescribing using a formulary ratified by the provider that takes account of:

- Local CCG formularies
- Adaptations and safety of specific medicines prescribed in secure environments as detailed in [RCGP Safer Prescribing in Prisons 2011](#) and [PHE Management of Persistent Pain in Secure Environments 2013](#)
- National resources in cost-effective prescribing such as [QiPP medicines use](#)
- Local procurement arrangements and QiPP initiatives

The arrangements for prescribing to patients of each service will be defined within the wider contractual framework for that service. It is expected that as a result of the roll out of the revised SystemOne prescribing module during 2014 and the subsequent procurement of future clinical IT systems for prisons, that the healthcare provider and any subcontractors will prescribe medicines using the electronic clinical IT system.

Generally where an in-reach or external prescriber (for example consultations by dental, mental health and secondary care providers) initiates a new medication, s/he will provide the first prescription with written agreements and procedures on repeat prescription linked to care review by the initiator. These arrangements should take into account local and regional/national decisions on where prescribing responsibilities should rest for individual medicines.

3.1 Prescription forms

- Providers **will not use** FP10 or FP10MDA prescriptions for routine prescribing but will use local individual prescription forms that comply with legislation.
- Providers who use individual prescription forms will have Standard Operating Procedures in place which ensure that prescription stationery is handled to the standards specified in "[Security of Prescription Forms Guidance](#)" (NHS Security Management, 2011).
- Providers who use prescriptions sheets (e.g. Prescription and Medication Administration Records) and charts (e.g. for syringe drivers) will give consideration to the security of blank sheets.
- Providers will source NHS FP10 and FP10MDA prescription pads (for emergency supplies and unplanned releases) via local arrangements within the Area Team. Providers who need to use them are responsible for ordering their own pads using the procedure specified by the commissioner.
- Lost, stolen or forged prescriptions will be reported to the Area Team using local arrangements
- Prescriptions will be written or computer-generated in line with guidance in the current BNF, and include dose and frequency.
- Prescriptions will include contact details which allow the prescriber to be contacted by the dispensing pharmacist if necessary.
- The process for handing out prescription forms to patients, their representatives or healthcare staff will take into account prescription security and patient confidentiality.
- Legal responsibility for prescribing lies with the prescriber who signs the prescription.
- Where the following activities are carried out there will be Standard Operating Procedures in place to ensure legal, safe and accurate prescribing:
 - The use of prescription sheets (e.g. Prescription and Medication Administration Records) and charts to include the management of multiple sheets and to minimise the risk of duplicate charts.
 - Transcribing prescriptions previously prescribed by a registered prescriber
 - Amending prescriptions
 - Verbal orders

- Prescribing for release and transfer
- Prescribing will be by generic name except where clinically inappropriate or when branded prescribing is specified in the area formulary or by the medicines management team

3.2 Supply arrangements

The arrangements for supplying medication to patients of each service will be defined within the contractual framework for that service. Such arrangements should ensure that sufficient access points and time is available for patients to receive their medicines to minimise delayed and omitted doses and maximise the safety of the supply including the supervision of medicines supplied not in possession. Should factors external to healthcare provision prevent this then the provider should report this to the NHS England Area Team commissioner.

3.2.1 In-possession medication

- Providers will have an in-possession policy and assessment tool that meets the requirements of [Medication In-possession. A guide to improving practice in secure environments](#) (National Prescribing Centre), [A Pharmacy Service for Prisoners](#) (DH) and [PHPQI Indicator 1.3 Medication Safety](#)
- The in-possession status of all patients admitted to the prison should be assessed by a locally ratified tool, supported by a patient compact and incorporating patient consent usually within 72 hours of reception.
- The tool should include elements that assess the individuals' clinical, mental and physical abilities to self-medicate safely and also contain a list that excludes specified medicines from in-possession or reduces the amount held in-possession due to security or high risk of self-harm.
- In-possession status should be assessed and reviewed/re-assessed as per the in-possession policy by trained staff groups and within specific points in the patient's care pathway or residence.
- Operational implementation of the in-possession should be routinely monitored and audited as part of the performance monitoring agreed with the commissioner. This should be used to inform the commissioner and provider that the in-possession policy and tool are being used effectively in practice to enable self-care with medicines where possible.

3.2.2 Supply and administration processes

- All supplies and administrations of medicines to patients should be within national guidelines (for example [Nursing & Midwifery Council Standards for Medicines Management](#) and [The Safe and Secure Handling of Medicines: a team approach \(Royal Pharmaceutical Society\)](#))
- The environment where medicines are administered or supplied should be fit for purpose and ensure the safety of the patient and staff minimising the risk of medicines diversion or errors of supply.
- The supply and administration processes should be underpinned by SOPs, delivered by trained and specified staff and monitored via audit and general "housekeeping" of the areas where medicines are stored for and used for supply and administration.
- Supply and administration should take place at pre-arranged times and sites agreed with the prison governor or their nominee and within a timescale and support from prison officers that enables the safe and secure supply to take place.

- Supply and administration of IDTS medication and other non-in possession doses of daily medicines must take place in the mornings before prisoners leave for work/education/court.
- It is expected that as a result of the roll out of the revised SystemOne prescribing module during 2014 and the subsequent procurement of future clinical IT systems for prisons, that the healthcare provider and any subcontractors will e-administer the majority of medicines using the electronic medication chart within the clinical IT system.
- The Provider will ensure that there are robust procedures in place to ensure administration charts / prescriptions match with the prescribing information entered on the clinical system, and all transcription procedures are minimised
- Where manual administration charts are used there are clear procedures for accurate copying of the prescribed medicines onto the chart and timely input of the administrations onto the clinical IT system.

3.2.3 Patient Group Directions (PGDs)

Providers who are commissioned to deliver a service using PGDs will develop and operate those PGDs in accordance with current legislation, NHS England Area Team procedures, and the [NICE Good Practice Guidance 2 Patient Group Directions](#) and subsequent guidance and resources available at:

<http://www.medicinesresources.nhs.uk/en/Communities/NHS/PGDs/About-us/>.

- Providers will have a policy in place for the development and handling of PGDs that covers the requirements above.
- Organisations which are listed in [legislation](#) as able to authorise their own PGDs will do so
- Those organisations which are not listed in legislation as able to authorise their own PGDs will arrange authorisation by the commissioner using Area Team procedures.
- A pre-authorisation checklist should be used. Some of the main points to consider are:
 - Suites of PGDs will include a description of how the various PGDs fit together and the criteria for selecting a particular medication, PGDs for antimicrobials will be considered only if the local consultant microbiologist has been involved in the development process
 - Any points noted as 'Cautions' will list the appropriate action to be taken if the caution applies
- PGDs will only be used where there is no opportunity for assessment by a prescriber who could issue a Patient Specific Direction.
- Supply or administration of the medication must be carried out by the professional who is operating the PGD, it cannot be delegated to another member of the team
- Providers are expected to consider the arrangements for the purchase, storage and supply of medication packs as specified in PGDs for take away medication. Packaging and labelling will meet regulatory requirements.
- Providers will arrange for the appropriate training of staff who will operate the PGDs
- Where a provider adopts a PGD written by another organisation, including PGDs provided by NHS England or Public Health England, the PGD will be signed by a governance lead or manager on behalf of the provider. That person is responsible for the governance arrangements for the use of the PGD within their organisation, and ensuring that each practitioner who operates the PGD is suitably qualified and signed up to it individually at that organisation.

3.2.4 In patient medication

- Where in-patient care is provided by the provider, standards and practice should be delivered to the same quality and governance frameworks as the requirements in this document.

- Self-administration of medicines by in-patients should be enabled where possible in line with previous in-possession of medication provision for the patient unless re-assessment outcomes dictate otherwise
- Providers must ensure that medicines are administered and supplied in a timely manner and by suitably trained staff for all routes of administration.

3.2.5 Verbal orders

- Providers who administer medication will assess the risks associated with verbal orders, issued in an emergency to authorise the administration or discontinuation of a prescribed medication, and when they are used, have a governance framework in place to manage those risks.
- Where verbal orders are used, providers will have a procedure in place to ensure that they are issued by a prescriber, and received, recorded and acted on by a designated practitioner.
- The procedure will specify the duration for which a verbal order will apply, and the process for obtaining the prescriber's written instructions
- The procedure will cover other methods of receiving remote instructions such as fax, email and text if applicable

3.2.6 Homecare

- The services provided by homecare medicine companies are excluded from Payment by Results (PBR)
- Providers will work with commissioners and NHS England Specialised Commissioning teams to maximise the use of homecare where appropriate to take advantage of savings on VAT and admission costs
- Where possible providers will use home care providers which have a formal NHS contract established to manage quality and cost-effectiveness in delivery of the service
- Any new arrangement must be agreed in advance with the commissioner. It should take into account the best practice guidance Homecare Medicines "[Towards a Vision for the Future](#)" DH November 2011

3.3 Medication review

Medication reviews take place in many settings and providers are encouraged to work together to provide a service that maximises the use of skill mix and access by prisoners to a review.

- For all types of review there will be a procedure in place which complies with the principles of medication review outlined in the [Guide to Medication Review](#) (National Prescribing Centre, 2008)
- The review will include considering the discontinuation of medication which is no longer effective or adhered to
- The Provider will ensure, through the above systems all prisoners will receive a medication review by an appropriate clinician within one month of admission and at least at 12 monthly intervals with shorter periods for medicines at high risk of abuse or diversion.

3.3.1 Clinical medication reviews

- Providers will ensure that their procedure includes the identification of patients for review based on risk factors such as number of medications, repeat medications, long term conditions, medicines at high risk of abuse or diversion and others in line with national service frameworks and best practice guidance.
- The procedure will include how patients who do not present for review are managed
- The procedure will include how the results of MURs and and NMS (see below) are used to trigger clinical medication reviews, and how patients are referred for MURs, and NMS
- The procedure will include how the results of adherence checks or cell searches (that suggest non-adherence to the prescribed regimen) are used to trigger medication

reviews. A consistent multidisciplinary pathway will be used to ensure any changes in medication are safe and handled in partnership with prison security, wing officers and relevant healthcare staff.

3.3.2 Pharmacy-led Medicines Use Review (MUR) and New Medicines Service NMS

- Pharmacy providers (internal and external) with an NHS Pharmaceutical Services contract meeting the conditions of the national [Advanced Service](#) may offer MURs and NMS with agreement by the healthcare provider
- Each pharmacist who provides MUR services will send a copy of their certificate (MUR) or self assessment form (NMS) to the operational manager for the provider. A pharmacy technician is able to provide this service within a prison environment but training must be the equivalent of that completed by pharmacists and accreditation of the pharmacy technician should be via a registered pharmacist.
- The provider will have an SOP to include how patients are identified for review. It is expected that 50% of MURs will be for those patients in the national target groups, and that the MUR will cover all patients' medicines, not just those in the target groups. It is expected that other patients will be selected based on the potential benefit of the MUR.
- There will be a documented justification for providing an MUR to a patient within 6 months of that patient having an NMS review.
- Patients will sign a consent form including the wording set out in the service specification when receiving an MUR/NMS
- The providers will record MURs and NMS in line with the national service specification, and completed MURs/NMS will be reported via the provider's medicines management committee who will oversee the use and outcomes of these reviews.

3.4 Duration of treatment

- Prescriptions will generally be for a maximum of 28 days or a single original pack with a documented review date
- Procedures should be in place showing the action to take should a medicine require supply once the review date has passed.

3.4.1 Repeat Prescribing

- Providers should develop and implement a system of repeat prescribing that is similar to that used in primary care by GP practices as detailed in the NPC Guidance [Dispensing with Repeats](#)
- Repeat prescribing processes should be underpinned by SOPs that define the roles and responsibilities of staff in the repeat prescribing pathway
- Where possible the provider should enable prisoners to request repeat prescriptions themselves
- Processes should be in place to monitor adherence to medicines on repeat which identify and state actions to take in the event that prescription requests suggest over or under-dosing of medication.

3.4.2 Continuity of Care

Admission arrangements: The provider should establish communication links with other providers including, general practitioners, and community pharmacies to ensure that adequate information about a prisoners medicines arrangements, (including any supplies of medicines) are transferred with the prisoner. Information from Medicine Use Reviews (provided by community pharmacists) should be used where appropriate.

There should be a policy for medicines management arrangements on admission including:

- i. Arrangements for medicines history taking and pharmacist review of medication including medicines reconciliation.

- ii. Communication with providers in primary care
- iii. Previously prescribed medicines are re-authorised, stopped or re-prescribed within 5 days of admission but a policy and processes are in place to allow current, prescribed medicines to be administered or supplied to patients on admission /transfer using the patient's own drugs (see section 3.1.6) or providing an internal supply prior to and after re-authorisation which avoids omitted and delayed doses.

Discharge arrangements : When a prisoner is discharged, the prison should ensure that the prisoner has sufficient medicines and dressings, in dispensed packs to ensure continuity of care and prisoner safety, until the prisoner can reasonably be expected to visit the GP. This will be for a minimum of 7 days.

The discharge summary will include

1. Full drug therapy on discharge with an indication of whether treatment should be continued after initial supply.
 2. Any changes to medication since admission with reasons for change including any medication initiated, dose changes or discontinued
 3. Any problems the prisoner may have in utilising their medicines effectively.
 4. Any monitoring of treatment required including anticipated increase/decrease dose
 5. Details of treatments tried in prison but which proved unsuitable
- Prisoners should be provided with appropriate information about obtaining further supplies of medication. If there are unusual arrangements for obtaining a product (for example a hospital supplied medicine) the prisoner and GP should be provided with the necessary information to pass on to the dispensing pharmacist.
 - Benzodiazepines should not normally be prescribed for or issued to prisoners on discharge from prison where their use has been initiated in prison unless as part of a de-tox programme.
 - IDTS prisoners requiring methadone on discharge will be issued with FP10MDA /FP10 forms for dispensing by community pharmacy or have firm prescribing and dispensing arrangements in place on discharge including unplanned discharges (e.g. from court).
 - The provider will work closely with other healthcare providers to ensure pharmaceutical needs of the prisoners are met on discharge or transfer.
 - Where ongoing Community Nurse involvement is needed for dressings (or in other circumstances) both the GP practice and community nursing teams should be advised.
 - Prisoners should not be discharged on VAC pumps (or equivalent) without the prior agreement of the commissioner.
 - If a prisoner is discharged with an FP10 to be dispensed at an external pharmacy the associated costs (including admin costs) will be recharged to the provider.

Other continuity of care requirements

- Where a prescription is written by someone other than the prison's medical practitioner (e.g. a secondary care clinician), there will be a system in place to communicate the prescription and any request for continuing prescribing to the prison medical practitioner within 14 days.

3.4.3 Managed repeat prescription services or repeat dispensing (pharmacy contractors)

- Pharmacy and appliance contractors providing this service will have a Standard Operating Procedure in place
- The contractor will have a record of the patient's request to be part of the service
- Requests for repeat prescriptions will be made at the explicit request of the patient or their representative. The contractor may operate a reminder system but will not request a prescription from the patient's surgery without their consent on each occasion

- Each time a prescription is requested, pharmacy staff will establish with the patient or their representative which items are needed on that occasion, and ensure that items which are not needed are not included on the request
- Pharmacy staff will check again on collection whether everything is needed on that occasion. Unwanted items will be marked 'not dispensed' and returned to stock as appropriate
- Pharmacists will notify the prescriber of items which should no longer be on the repeat prescription list
- The patient will be given their most recent repeat request form, including any communication from their surgery (or be provided with a copy)

3.5 Prescribers

3.5.1 General

- Providers will ensure that their prescribers have access to clinical supervision, Continuing Professional Development, up to date information sources, relevant information about prescribing policies and practice
- Providers will ensure that prescribers are registered as prescribers with the relevant governing body, and that any restrictions on their prescribing are adhered to
- Providers will maintain a list of prescribers and their status, with specimen signatures
- The commissioner is responsible for setting up and updating FP10 prescribing arrangements with NHS Prescription Services. Providers will use the form provided to notify the commissioner of any new prescribers, including non-medical prescribers, and changes of name, location or status of prescribers.
- Prescribers are responsible for ensuring that arrangements are in place for drug monitoring where relevant to the medication prescribed.
- Prescribing should be undertaken via e-prescribing processes using the clinical IT system. Paper-based prescribing should be minimised to areas where this improves governance or be phased out.

3.5.2 Non-medical prescribers

- Providers will have a non-medical prescribing policy to cover the activities of nurses, pharmacists and other allied health professionals who become qualified prescribers. The policy will include:
 - The governance arrangements for assuring safe and effective non-medical prescribing
 - Employer liability
 - Professional indemnity
 - CRB checks
 - Prescribing for self, family and friends
 - Repeat prescriptions
 - Off-label prescribing and unlicensed medicines
 - Regular reviews of prescribing and identification of CPD needs
- Non-medical prescribers will:
 - Be registered as prescribers with the relevant governing body and comply with their code of practice
 - Act as prescribers only when formally contracted to do so
 - Agree a scope of practice with their employer and prescribe within this scope only
 - Ensure that they are remain up to date with current legislation on prescribing and the safe management of Controlled Drugs

3.6 Formulary

Organisations will ensure that staff are aware of the local and national formularies and guidelines and that they prescribe and advise within these parameters.

3.6.1 Local Area Prescribing Committee

- Organisations with prescribing responsibilities are expected to participate in and abide by the decision making processes of the local Area Prescribing Committee, which develops prescribing guidelines and manages the entry of new drugs into the local health economy.

3.6.2 Locally implemented Formularies

- Clinicians and pharmacists will recommend, prescribe and dispense medicines, dressings and appliances from the locally developed or agreed formulary except when variance has been agreed with the commissioner
- The locally used formulary should be developed to the standards recommended in the [NICE Good Practice Guidance 1 Developing and updating local formularies](#)
- Prescribing will be within agreed policies, formularies and care pathways, which will include both the choice of drug, clinical audit requirements and reporting mechanisms.
- Formularies should exclude those defined by the Audit Commission as [Drugs of Limited Clinical Value](#), and those defined in the BNF as 'less suitable for prescribing'. These will only be prescribed in certain circumstances – justification for their use must be documented
- Providers will support formulary prescribing by actively reviewing all patients on non-formulary medicines and switching to formulary drugs where appropriate
- A decision to treat outside the local formulary list is a clinical decision. The provider should have a process which considers and agrees prescribing outside the formulary via a formal exceptional case process where outcomes are clearly documented in the clinical record.

3.6.3 NICE guidance

- Providers are expected to comply with NICE Technology Appraisals.
- The commissioner, in conjunction with the Area Prescribing Committee, will determine when and how NICE Clinical Guidelines are to be implemented

3.6.4 Shared- and continuing- care agreements

- For drugs subject to a shared- or continuing-care protocol, specialists will continue prescribing until a patient-specific agreement has been put in place with the prisoner medical practitioner
- When a shared- or continuing-care agreement is in place, specialists and the prisoner medical practitioner will undertake the responsibilities outlined in the protocol

3.6.5 Unlicensed products

- The provide should have a policy for the use of un-licensed medicines
- Unlicensed drugs, or drugs used 'off label', will only be included in the formulary where there is a substantial body of published evidence and support from local clinicians.
- The BNF can be used to check whether a product is licensed and to identify suitable licensed alternatives.
- Many unlicensed medicines are 'special order' products which can be expensive.

3.6.6 Prescribing for patients with swallowing difficulties / feeding tubes

- Providers who are involved in prescribing medication for adult patients will have a policy in place to manage patients with swallowing difficulties or feeding tubes. The policy will take into account the fact that special order liquid medicines are unlicensed and can be expensive, and should adopt the following stepwise approach:
 1. Check that the medication is still needed
 2. Use a licensed preparation (e.g. liquid, dispersible tablet). Consider changing to a different drug of the same class in order to use a licensed preparation
 3. Use a licensed medicine in an unlicensed manner (disperse tablets in water, crush tablets, open capsules). [Guidance](#) is available on the ways in which

different preparations can be treated, their suitability for use with feeding tubes, and how they can be administered

4. Where no licensed option is suitable, consider an unlicensed liquid special

- The prescriber must give clear instructions in writing for inclusion in the care plan, and the same instructions should appear on the label, in order for staff to be able to administer a product in an unlicensed manner. Patients should be informed that an unlicensed preparation is being prescribed.

3.6.7 Prescribing for covert administration

Providers who are involved in administering medication will consider current legal and best practice frameworks and make a full assessment of the capacity of the patient to refuse their medication before undertaking covert administration.

3.6.8 Availability of NHS treatment

- Prescribers may not issue private prescriptions to their NHS patients unless the item is not available on the NHS.
- Where private prescriptions are issued the patient must pay for the medicines supplied and any administration charges agreed by the prescriber and/or dispensing pharmacy.
- Where an NHS doctor has referred a patient to a consultant for advice, privately or otherwise, the referring doctor should issue NHS prescriptions, from the current area formulary, for ongoing treatment.
- NHS prescriptions are not available to patients who refer themselves for private assessment and need ongoing treatment as part of that care. Patients must be re-assessed under the current agreed NHS criteria before transferring to NHS Care and treatment

3.6.9 High Cost Drugs

- Providers will comply with local and national High Cost Drugs policies
- Prior approval will be sought using the appropriate local or national process
- Payment will only be made where the drug has been used for an approved indication and the relevant criteria are met

3.6.10 PbR exclusions

- Providers will notify or obtain prior approval from the commissioners for PbR excluded drugs for new patients or for patients transferred from another prison.
- Providers will routinely prescribe lower cost drugs where these have been proven to be clinically effective
- Providers will not prescribe PbR excluded drugs where there is a clinically appropriate, non-excluded drug unless specifically agreed in writing
- Providers will ensure that PbR excluded drugs (and devices) charged are as listed within the PbR exclusions list (for that year) and only used for approved indications

3.6.11 Individual Funding Requests / Exceptional cases

- Requests for individual drug funding may be made by a clinician, in line with the relevant CCG or NHS England policy, when there are exceptional clinical circumstances for the patient, the associated published evidence supports the requested use and there is evidence that the particular patient will benefit from the treatment

3.6.12 Cancer drugs

- Cancer drugs will be prescribed in line with relevant Cancer Network and NHS England Specialised services policies

- Notification proformas will be used where available including for treatment from the Cancer Drug Fund

3.6.13 Dietetic products

- Gluten free products can be prescribed for those with established gluten enteropathy, confirmed by specialist diagnosis and biopsy. The range of products and quantities prescribed will be in line with current guidance (www.coeliac.org.uk) and take account of advice from the CCG or Area team
- Oral nutrition products will be prescribed in line with the of advice from the CCG or Area team only after the 'food first' approach has been tried

3.6.14 Homely remedies

- Providers will have a policy and related SOPs and protocols on the treatment of minor ailments and the use of homely remedies and self-purchased medicines by their service users. Any supply or administration of these medicines should be documented in the clinical record.
- Where patients are charged for these medicines please see section 3.1.3
- In all cases of supply by the provider patients should have access to a pharmacist or nurse who can provide them with advice about the medicine they are accessing.
- All supplies should include access to the Patient Information leaflet and should not be re-packaged by the provider unless this is via an on-site pharmacy within regulatory parameters.

3.6.15 Appliances

- Where local formulary covers a type of appliance, formulary items only will be prescribed as for medicines above
- Where the formulary does not cover a type of appliance, the prescriber should take the cost into account when prescribing and seek specialist advice where necessary
- Only appliances listed in Part IX of the [Drug Tariff](#) are available on NHS prescription. Other appliances must be supplied directly by the provider or alternative arrangements made.

3.6.16 Medicines for clinical trials

- Providers will seek the appropriate ethics approval before undertaking clinical trials which should be conducted according to current Good Clinical Practice standards. Any trial which may result in additional activity or change to existing pathways will be agreed in advance with the commissioner.

4 Advice to patients

4.1 Drugs for self purchase

- In addition to section 4.6.14, patients will be made aware of medicines that are available to buy via the Canteen List (National Product List), and advised to purchase them instead of acquiring them via prescription.
- Providers will need to ensure that if paracetamol is included in the Canteen List, that a risk assessment is completed and documented and a process for monitoring purchases is put in place.
- Providers will ensure that access to a pharmacist for medicines advice is in place as per [A Pharmacy Service for Prisoners](#)

4.2 Promotion of self care

- Providers will offer opportunistic brief interventions whenever appropriate to advise patients and service users on lifestyle measures that will enable them to get the best from their medication.
- For non-medical conditions such as mild skin and scalp conditions, the healthcare provider will have polices and information for patients and staff that enable patients to purchase items for self care

- Providers should encourage self care and self management of long term conditions that supports clinical pathways and maximises clinical outcomes in line with national guidance.

5 Governance

Providers are expected to have governance arrangements in place appropriate to the services they provide. The following governance arrangements are examples of those which not specific to medicines management and are not covered in detail in these standards:

- Information governance
- Complaints and incidents
- Record keeping
- Mental capacity
- Business continuity
- Safeguarding
- Consent
- Whistleblowing
- Bribery
- Fraud
- Theft

5.1 Standard Operating Procedures

- Providers will develop Standard Operating Procedures (SOPs) to describe the processes of handling and managing medicines
- SOPs will be formally approved by the provider, and reviewed at least every 2 years
- SOPs will indicate who is authorised to carry out each activity, be signed by staff using it and indicate what training is necessary, and what records will be kept

5.2 Working with industry

- Providers will ensure that they have a policy on commercial sponsorship and interactions with the Pharmaceutical Industry based on Department of Health guidance "[Commercial Sponsorship ethical standards for the NHS](#)".
- Providers planning to enter into joint working arrangements with the Pharmaceutical industry will adhere to their own equivalent policy based on Department of Health "[Best Practice guidance on Joint Working between the NHS and Pharmaceutical Industry and other Relevant Organisations](#)".
- Policies will apply to all employees including non-medical prescribers and non-clinical staff
- Samples of medicine will not be accepted by staff or made available to patients

5.3 Medication/Appliance Safety Incidents

- Providers will each maintain a medication/appliance safety incident log and receive error logs from subcontracted pharmacy service providers where relevant. These medication/appliance related incidents will also be reported to the commissioner in line with the commissioner's incident reporting or contract monitoring processes.
- The log will be reviewed regularly and providers will be able to provide evidence that they have identified and acted on trends and put corrective action in place to prevent recurrence of errors.
- Medication Safety incidents will be routinely reported via the provider's wider incident reporting process and in line with NHS England Area team and national incident reporting requirements

- Handling of Medication Safety Incidents will usually be led by the Medicines Management Committee which also receives information about medication Security Incident Reports.
- Medication Incident reporting should include clinical, operational and incidents of suspected or identified abuse or diversion of medicines.

5.4 Prescribing Advice

- Advice provided by healthcare professionals e.g. pharmacists, nurse practitioners, nurses, dieticians, physiotherapists and others needs to be within agreed local guidelines and any recommendations to prisoners or other clinicians that may affect prescribing should be within these parameters.

5.5 Adverse reactions

- Suspected adverse reactions to medicines, particularly black triangle medicines under intensive monitoring, can be reported to the MHRA by anyone including non-clinical staff and patients.
- Reports can be made online at www.yellowcard.gov.uk or using the form in the BNF

5.6 Medicines Safety alerts

Providers will have a process for receiving, acknowledging and acting on medicines safety alerts, including drug recalls, whether national or local.

5.7 Stock Control

- The Commissioner requires regular stock checks and a top up service to be carried out within each of the prisons to minimise the risk of treatment delays or use of expired stock.
- Items which are required for clinical emergencies, where required, should be in clearly marked and in tamper-proof emergency boxes, at accessible sites. Regular checks should be made by the Contractor on these boxes to ensure items are replaced after use or time expiry. All stock order lists will require countersignature by a prescriber.
- The Commissioner requires that appropriate arrangements are made for the secure transportation of medicines and controlled drugs within the prison in accordance with relevant legislation and guidelines.

5.8 Medicines Waste

The Provider shall ensure that it has suitable processes in place for the safe disposal of medicines in line with national waste regulations.

5.9 Audit

- Providers will have a programme of annual audit in line with their organisation's clinical governance framework, their professional code of conduct, individual service specifications and their NHS contractual requirements.
- The Provider will participate in any relevant clinical audit related to medicines developed by East and South East England Specialist Pharmacy Services.
- The Provider will deliver audits in:
 - Key therapeutic areas, e.g. formulary adherence, pain management, antibiotic prescribing.
 - Areas of clinical practice requiring medicines management advice e.g. NICE, National Service Frameworks (NSFs), NPSA alerts, and local guidance
 - Operational delivery of medicines handling e.g. In-possession implementation; medicines administration