Independent Clinics

Core Standards

Registration & Inspection Unit

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Introduction

Aims
This document sets out the Standards that registered providers are expected to apply to their service. These are the minimum standards required and the Regulation of Care Act requires that the DHSC considers these standards when making regulatory decisions; there are opportunities within the Standards for registered providers to be creative, innovative and dynamic when applying them to their service, and providers should use them as a baseline from which to deliver and develop services to the service users who use them.

Regulatory Context
The Regulation of Care Act (ROCA) 2013 and associated regulations replaced existing legislation on the Isle of Man that governed the care of adults and children receiving services that were subject to regulation. This has resulted in some services being re-categorised and a number of services not previously subject to regulation being included.

These standards will form the basis for judgements made by the DHSC as to how providers are meeting their obligations under the ROCA, the Registration Regulations and the Care Services Regulations and will therefore consider the degree to which a regulated service complies with the standards when determining whether or not a service should be registered or have its registration cancelled, or whether to take any action for breach of regulations.

Structure and Approach
The standards for independent clinics focus on ensuring that service recipients receive treatment and services that are safe and quality-assured and are, as a minimum, compatible with standards in the NHS. They are the core standards applied to a range of clinics providing specific services and are supplemented by service-specific standards that apply to each prescribed service coming under the definition of an independent clinic. Therefore not all the core standards will apply to every service. Each prescribed service will have included within their service specific standards a guide to which of the core standards are not applicable to their particular service.

Each standard is preceded by a statement of the intended outcome for service recipients. Whilst the standards are qualitative – they provide a tool for judging if service recipients are receiving safe and quality-assured treatment and services – they are also measurable. Regulators will look for evidence that the requirements are being met through:

- Discussions with service recipients, staff and managers and others;
- Observation of arrangements within the clinic;
- Scrutiny of written policies, procedures and records.

The Standards have been developed to require and encourage registered providers/managers to deliver services to service recipients that are:

- safe
- of measurable quality
- delivered by competent practitioners
- in accordance with specific benchmarks of good practice
- in accordance with service recipient expectations
Glossary

**Accident**
Any unexpected or unforeseen occurrence, especially one that results in injury or damage.

**Accident report**
A written report of an accident. The format of the report is laid down in Health and Safety Legislation.

**Accountability**
The state of being answerable for one’s decisions and actions. Accountability cannot be delegated.

**Audit**
The process of setting or adopting standards and measuring performance against those standards with the aim of identifying both good and bad practice and implementing changes to achieve unmet standards.

**Adverse health events**
An incident, accident or occurrence, relating to clinical systems or procedures which results in harm, or an injury, or near miss to a service recipient/user or member of staff.

**Advocate**
An individual who acts independently on behalf of, and in the interests of, service recipients/users who may feel unable to represent themselves in their contacts with a health care or other facility.

**Aim**
Overall purpose or goal of a department or service.

**Annual report**
A report, written annually, which details progress over the last year and plans for the following year, which includes financial and activity statements.

**Care plan**
A document which details the care and treatment that a service recipient receives and identifies who delivers the care and treatment. This term covers the term ‘individual plan’.

**Carer**
A person who may be paid or unpaid, who regularly helps another person, often a relative or friend with domestic, physical, emotional or personal care as a result of illness or disability. This term incorporates spouses, partners, and parents, guardians, paid carers, other relatives, and voluntary carers who are not health professionals.

**Consultant**
Medical Practitioner who works independently without supervision.

**Continuing professional development (CPD)**
Activities which provide education and training to staff. These may be used to prepare for specialisation or career development as well as facilitating personal development.
**Contract/agreement**
The document agreed between providers of health care and the purchasers of health care detailing activity, financial and quality levels to be achieved.

**COSHH**
Acronym for the control of substances hazards to health legislation.

**Food hygiene**
Taking all measures necessary to ensure the safety and wholesomeness of foodstuffs.

**Hazards**
The potential to cause harm, including ill-health and injury, damage to property, plant, products or the environment, production losses or increased liabilities.

**Incident**
An event or occurrence, especially one which leads to problems. An example of this could be an attack on one person by another within a service.

**Induction programme**
Learning activities designed to enable newly appointed staff to function effectively in a new position.

**Job description**
Details of accountability, responsibility, formal lines of communication, principle duties, entitlements and performance review. A guide for an individual in a specific position within an organisation.

**NMC**
Nursing Medical Council

**Organisation**
The term used in this publication to describe the entire organisation, as opposed to the term service, which is used to describe one part of the organisation (see also service).

**Outcome**
The end result of care and treatment that is the change in health, functional ability, symptoms or situation of the person, which can be used to measure the effectiveness of care and treatment.

**Personnel**
All those who work in the regulated establishment/agency i.e. those with practising privileges as well as staff.

**Policy**
An operational statement of intent in a given situation.

**Practicing Privileges**
Someone who is registered with the appropriate regulatory body, appropriately recruited and trained, qualified and experienced to give treatment.
**Procedure**
The steps taken to fulfil a policy.

**Quality Assurance (QA)**
A generic term to cover the review of the quality of services provided, along with interventions designed to improve that quality through the remedying of deficiencies identified by the review process. The review may include both qualitative and quantitative measurements and may or may not relate to clearly stated standards.

**Risk management**
A systematic approach to the management of risk, to reduce loss of life, financial loss, loss of staff availability, staff and service recipient/client/user safety, loss of availability of buildings or equipment, or loss of reputation.
Standard 1 - Introduction, Assessment

**OUTCOME**

**Service recipients must receive clear and accurate information about the service, their treatment and its likely costs.**

1.1 The Clinic must have available for prospective service recipients a statement of purpose and a service recipient guide expressed in a format suitable for the profile of the clinic. The statement of purpose must contain the information set out in Schedule 3 of the Care Service Registration Regulations.

1.2 The service recipient guide must be reviewed annually to ensure the information in it remains up to date and the review date recorded.

1.3 The guide must include information about:
   - The services philosophy and ethos.
   - The terms and conditions of treatment.
   - A copy of the clinic’s complaints procedure.
   - A statement of service recipient rights.
   - An outline of the policies and procedures that affect the service recipients receiving treatment.
   - A brief outline of staffing arrangements, training and qualifications.

1.4 Service recipients must be actively encouraged to make suggestions and there must be a system in place to enable comments about the service recipient guide.

1.5 The registered person must ensure that information on the treatment provided by the clinic is not misleading and all information provided must be accurate and any claims made in respect of treatment are justified.

1.6 Any advertisements must meet the requirements of the Advertising Standards Authority.

1.7 Any information given to the media must respect the confidentiality of service recipients.

Standard 2 - Quality of Treatment and Care

**OUTCOME**

**The treatment and care provided must be person-centred. Treatment must be provided in line with relevant clinical guidelines.**

2.1 The registered person must have a policy and procedure in place to ensure that the treatment provided is person-centred. The policy must cover how:
   - assessment of service recipients health needs is timely, appropriate and accurate;
   - service recipients are informed of the recommended interventions for treatment and/or care;
• service recipients must give verbal consent to all intimate examinations, and must be offered a chaperone if undergoing such an examination, or are able to bring a relative or friend with them if they wish;

• service recipients, and their relatives if appropriate, must be consulted about the planning and delivery of services provided to them, which includes taking into account their preferences and requests;

• service recipients must have access to their health records in line with the:
  - Data Protection Act 2018
  - recommendations of the Caldicott Committee report and
  - guidelines from professional bodies.

• services are provided in such a way that facilitates are accessed by service recipients of all abilities.

• how privacy, dignity and confidentiality are respected at all times.

• service recipients are addressed by their preferred name and title; and are treated with courtesy, consideration and respect.

2.2 DH guidance (Department of Health Guidance Reference Guidance to Consent for Examination or Treatment) including consent by children and the concept of ‘Gillick Competencies’ must be followed.

2.3 Clinical procedures must be explained to service recipients and the implications of the treatment and any options must be given to enable them to give valid consent or refusal.

2.4 Service recipients must give written consent before receiving treatment where:
  • the treatment or procedure is complex, or involves significant risks or side-effects
  • general/regional anaesthetic or sedation is to be used
  • clinical care is not the primary purpose of the procedure
  • there may be significant consequences for the person’s employment, social or personal life
  • the treatment is part of a project or programme of research.

2.5 Completed consent forms must be kept with the person’s notes. Any changes to a form must be initialled and dated by both service recipient and, if appropriate, a health care professional.

2.6 There must be a written policy and procedure to follow when the person does not have the capacity to give valid consent to treatment. (In the absence of capacity legislation on the Isle of Man, the guidance provided by the Department is to be followed).

2.7 There must be facilities for confidential discussions with health care professionals that ensure privacy.

2.8 Service recipients who choose not to discuss health related matters with members of the opposite sex receive, where possible, consultations with health care professionals of the same sex.
2.9 There must be written policies on the prevention of harassment and bullying of service recipients by staff and or other service recipients, in line with the Nursing and Midwifery Council. Practitioner/client relationships and the prevention of abuse.

2.10 The management of specific conditions must take account of evaluations by the National Institute for Clinical Excellence (NICE) in relation to effective clinical practice, service recipient safety and specific clinical guidelines from the relevant medical Royal Colleges, healthcare professional institutions and the NHS National Service Frameworks.

2.11 Training for health care professionals must be provided to ensure the individual needs of service recipients are met.

2.12 Clinical staffing levels must be sufficient to allow attention to the physical care needs of the service recipients and to provide pain relief and symptom control as required.

2.13 There is must be a written resuscitation policy for the clinic, which is:
   - developed in discussion with (as a minimum) senior health care professionals
   - in line with Resuscitation Council (UK) guidelines;

2.14 The resuscitation policy must be brought to the attention of all personnel.

2.15 There must be a member of staff on duty at all times trained in basic resuscitation techniques with up-date training on an annual basis.

### Standard 3 - Environmental and Personal Safety and Comfort

#### OUTCOME
There must be systems, checks, policies, procedures and staff training in place to ensure that service recipients’ dignity, well-being and safety is promoted and protected.

3.1 The registered person must have written processes that comply with relevant guidance and instruction to ensure the safety of the premises and environment.

3.2 Robust policies, procedures and training that enable service recipients to be safeguarded and protected from poor practice and abuse.

3.3 All staff must have access at all times to a detailed process that describes the steps they need to take if they receive an allegation or suspect abuse is occurring.

3.4 There must be a whistle blowing policy that is available to staff. Detailed records must be made and retained on issues raised around safeguarding. A copy of the most current Isle of Man Adult Protection Procedures must be read, understood and complied with by all staff.

3.5 Mandatory safeguarding training must be undertaken within 6 months of appointment. Staff must be aware of the types of abuse. Prior to the training, and within one week of the start date, the registered person must explain the safeguarding process to the new employee.

3.6 The clinic must have a complaints procedure that is written in plain language, displayed at the service and accessible to all. The complaints policy and/or procedure must include the following:
• provides assurance to service recipients receiving a service that their complaint will be taken seriously and there will be no retribution for making a complaint.
• provides information as to who the complaint may be referred to if not satisfied with the outcome.
• provides information on how service recipients can access an independent advocate to support them in making a complaint.
• makes appropriate provision for handling any complaint against the registered provider/manager of the service

3.7 The registered person must ensure that when complaints are accepted they are recorded. The complainant receives a written acknowledgement and a written outcome.

3.8 Fire precautions and fire safety must be managed in the clinic:
• the clinic must have a written Fire Risk Assessment that is compliant with the Isle of Man Fire Safety guidance and instructions.
• staff must be trained in fire within three months of commencing employment.
• records must confirm that weekly alarm tests monthly firefighting equipment (including emergency lighting) checks, and fire drills carried out at least twice per annum are carried out.
• compliance with the Isle of Man Fire Safety Department requirements, recommendations and or advice must be evident.

3.9 The registered person must makes available a range of policies and procedures that support safety, health and hygiene and ensures the clinic complies with relevant legislation.

3.10 Staff must have received training and follow robust policies in relation to cross infection and hygiene control and must be able to demonstrate their understanding and practice in their routines.

3.11 Advice, guidance and records in relation to the Control of Substances Hazardous to Health Regulations (COSHH) 1999 must be maintained.

3.12 Reporting Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) must be complied with and recorded.

3.13 Electricity at Work Regulations 1989 must be complied with. A certificate of conformity/safety is available for the clinics electrical installations that are in compliance with 'The 18th edition, Wiring Regulations' or equivalent. Portable Electrical Appliance tests must be carried out and recorded in compliance with current guidance and instruction.

3.14 A system must be place to ensure regulation of water temperature designed to control the risk of Legionella.

3.15 Central heating and boiler maintenance must be carried out and recorded.

3.16 Passenger lifts and pressure vessels must have periodic inspections by a competent person and records are kept.
3.17 Where there is a medical gas line(s), there must be a written procedure for any interruption. The procedure must be authorised by the registered manager or by a person authorised by the registered manager.

3.18 The service must have in place, and displayed, appropriate current public liability insurance.

3.19 Waste must be segregated into clinical and non-clinical items and stored in colour-coded bags and containers.

3.20 Clinical waste must be labelled to enable it to be traced back to its point of origin.

3.21 Clinical waste stored outside the building must be kept in locked containers.

3.22 All health care workers (including practitioners with practising privileges) must comply with Department of Health guidelines on health care workers infected with blood borne virus (hepatitis B, hepatitis C, HIV).

3.23 There are must be written instructions for health care workers and practitioners with practising privileges on the steps required by the clinic in order to ensure their compliance and notification of infection status in line with the guidelines.

3.24 All health care workers who perform exposure-prone procedures must provide evidence of their vaccination status with regard to hepatitis B. Staff must be tested for, and vaccinated against, hepatitis B if there is no evidence of previous vaccination produced.

3.25 The clinic must keep vaccination records for all health care workers employed and all practitioners with practising privileges.

3.26 Medical devices intended for single use must not be reprocessed for reuse and reusable medical devices must be decontaminated in accordance with legislative and best practice requirements.

**Standard 4 - Equipment and Supplies**

**OUTCOME**

All equipment must be checked for safety and be maintained in good condition. All supplies must be suitable and safe for purpose

4.1 There must be a comprehensive risk assessment and a maintenance plan that covers all areas of the premises and the equipment.

4.2 Equipment must be installed, checked and serviced in compliance with the manufacturer’s instructions.

4.3 Equipment must be not modified unless the manufacturer’s advice has been sought, and no risk has been identified.

4.4 All equipment must conform to current health and safety regulations and, where appropriate, there is a planned preventive maintenance and replacement programme.

4.5 Records must be kept of the maintenance and servicing of all equipment.
4.6 All stock products used in the clinic must be used in date order and within expiry dates.

4.7 Heat sensitive and/or light sensitive items must be stored in a controlled environment.

**Standard 5 - Staffing**

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<th>OUTCOME</th>
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<td>Staff must be recruited following a rigorous and robust recruitment programme. There must be sufficient numbers of trained competent staff to provide services</td>
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5.1 The registered person must have an Equal Opportunities Employment Policy. The policy must outline that applicants are treated equally and fairly when applying for employment. Robust tests must determine the applicant’s character and fitness for the post. Current employment legislation must be followed.

5.2 Staff must be provided with a clear definition of their roles and responsibilities (job description etc.). Contracts of employment and/or terms and conditions of employment must detail their employment obligations and be signed by both parties.

5.3 Staff files (including volunteers) must contain:
   - a completed application form and interview notes
   - two references (one of which must be the applicant's last employer).
   - evidence of a relevant Disclosure and Barring Scheme check - renewed every 3 years unless the option of portability is taken up.
   - work permit (where applicable).
   - a statement that the applicant has no known medical condition that will debar them from carrying out their duties.
   - certificates of qualifications and achievements, for qualified nurses an up to date PIN number.

5.4 Successful applicants must be employed under a minimum 3 month induction/probationary period which consist of regular one to one meetings with their direct line manager. A written induction programme must be followed and signed off by supervisor and inductee.

5.5 All new staff working directly with service recipients must work supernumerary during their first week, shadowing experienced workers.

5.6 Induction training for staff working directly with service recipients must consists of all appropriate mandatory training including:
   - First aid
   - Moving and handling (if appropriate)
   - Medication training
   - Physical Intervention
   - Safeguarding/Adult and Child Protection.
- Fire Training
- Communication
- Food Hygiene (if appropriate)
- Health and Safety
- Infection Control
- Value based training (privacy dignity, resident’s rights etc).

5.7 Training for ancillary staff must be designed to meet the needs of their specific role and induction training must consist of mandatory training relevant to that role.

5.8 The training must be completed within the induction/probationary period time scales, unless extended by agreement; the employee’s line manager along with the employee must reviews and evaluates the effect of the training on performance prior to confirming the appointment in writing.

5.9 Individual training needs and gaps must be identified by the manager of the service and the staff member during an on-going programme of regular one to one/supervision.

5.10 All staff must have an annual appraisal of their performance.

5.11 Records of one to one supervision sessions and annual performance appraisals must be maintained on the person’s individual file and a copy provided to the person.

5.12 All health care professionals must abide by published codes of professional practice relevant to their professional role.

5.13 There must be written disciplinary procedures for staff. These must be included in the contract of employment, practising privileges agreement, or staff handbook.

5.14 All health care professionals must take part in the on-going continuing professional development (CPD) required by their professional body and /or Specialist College, including revalidation requirements of the GMC.

5.15 A written training policy and programme must be in place to ensure that non nursing staff who provide care to service recipients are trained and competent and that qualified staff maintain and update their training. The programme contains a commitment to have a minimum of 50% of its care/support staff trained to QCF (Quality Care Framework) level 2/3 standards (or equivalent), according to job role. The training programme must have provision for refresher training to take place. All other staff must be trained for their specific role within the service.

5.16 All training programmes must be delivered by competent and knowledgeable trainers, and are regularly evaluated to ensure continuing fitness for purpose.

5.17 Following all staff training an evaluation check must be carried out and recorded by the manager of the service.
Standard 6 - Management, Quality and Improvement

OUTCOME
The registered manager must be qualified and competent to manage the clinic. Service recipients must be consulted about how the clinic is run and their opinions must be taken into account. The clinic must have an annual development plan that makes provision for development and improvement.

6.1 The registered manager must have a relevant professional qualification and experience and hold an appropriate management qualification in accordance with the service specific standards in place.

6.2 Improvements and development items must be identified by the registered manager; the staff team and the people receiving treatment. Those forming part of the management team must be assisted and supported to develop their management skills.

6.3 The registered person must ensure staff have access to policies and procedures. Service recipients, receiving treatment must have access to copies of the policy and procedure documents.

6.4 Policy and Procedure documents must be regularly reviewed and dated on the front cover to indicate the date of the review and when the next review is due.

6.5 Service recipients receiving treatment and their relative/representative and those visiting the clinic, including healthcare professionals, must be provided with opportunities to give their views on how the clinic is run.

6.6 Formal quality assurance systems must be in place and the registered person must use a range of tools to measure the quality of the service provided. This will include:

- numbers and types of complaints received and any learning resulting from this
- comments and compliments about the service from a range of stakeholders
- accident and incident reports
- observations of those using the service
- views of staff working at the service
- the outcomes of clinical audits
- the use of comparative information on clinical outcomes
- evaluation against research findings and evidence based practice
- effective information and clinical record systems
- procedures for identifying and learning from adverse health events and near misses.

6.7 An annual report must list the success of the service and introduces a written development/improvement plan based on the outcomes of the quality assessment exercise. The plan is displayed and available to all.

6.8 The registered person must have in place systems to check and monitor staff activity to ensure compliance with the terms and conditions of their employment and the clinic’s policy and procedural requirements.
6.9 Paperwork, records and documents must be maintained in good order, be legible and kept up to date.

6.10 A written policy must be displayed on the clinic premises informing service recipients of their rights to access their records at any time.

6.11 The registered person must ensure the holding of personal information complies with the principles outlined within the Data Protection Act 2018.

6.12 The service must have a quality assessment system and compile an annual report. The annual report must include assessment of:

- the premises
- staffing levels and skills
- customer satisfaction
- complaints

Standard 7 - Practising Privileges

OUTCOME
Service recipients must receive treatment from appropriately recruited, trained and qualified health care professionals.

7.1 Where health care professionals are granted practising privileges (ie the grant to a person who is not employed in the establishment of permission to practise on those premises) there must be written policies and procedures on allowing practising privileges.

7.2 The following pre and post-employment checks must be carried out before a health care professional is granted practising privileges:

- that the practitioner is registered with the appropriate professional regulatory body
- that the practitioner is trained and is experienced in the type of treatment they are given practising privileges to perform
- that the practitioner declares whether or not they are:
  - is currently the subject of any police investigation and/or prosecution, in the UK or any other country
  - has ever been convicted of any criminal offence required by law to be disclosed, received a police caution in the UK, or a criminal conviction in any other country
  - is currently the subject of any investigation or proceedings by anybody having regulatory functions in relation to health/social care professionals including such a regulatory body in another country
  - has ever been disqualified from the practice of a profession or made subject to specified limitations following a fitness to practise investigation by a regulatory body, in the UK or another country.
that the practitioner is interviewed before being granted practicing privileges and that records of interview and written references are retained.

that qualifications relevant to the post applied for are verified by validation at the interview.

that the practitioner is appropriately registered, whether that registration covers the duties to be undertaken and whether there are any restrictions in place or investigations underway by the relevant regulatory/licensing body.

that employment references are sought from the two most recent employers prior to making an agreement.

that a DBS check is carried out at the level required for service recipients working directly with service recipients and has been renewed every 3 years unless the option for portability has been taken up

that indemnification is checked and authenticated

that documentary proof is maintained of the continuing registration with the respective professional regulatory body

that the procedures for practitioners to follow when gifts are offered from service recipients, and what may and may not be accepted, are set out

that the practitioner who is offered practising privileges has his/her identity confirmed through the presentation of a valid birth certificate, and passport or driving licence

that there are arrangements in place for ensuring the validity of work permits are verified and that their status is clarified.

7.3 There must be a written agreement with the practitioner setting out:

the details of the practising privileges, which includes a stated requirement of the practitioner’s availability to attend the establishment within a certain time limit if notified of a problem with a service recipient.

they must comply with the organisation’s policies and procedures.

that the practitioner is required to place a copy of all clinical notes relating to care or treatment at the clinic in the service recipient’s record retained by the clinic.

7.4 There must be arrangements in place for continuing professional development.

7.5 The practitioner must be made aware of the current policies and procedures in the clinic, and a list of the relevant policies and procedures that he or she is expected to be familiar with, is provided.

7.6 Practising privileges must be reviewed for each practitioner every two years, as a minimum and more frequently if concerns arise.
Standard 8 - Risk Management

OUTCOME
Service recipients, staff and anyone visiting the premises must be assured that all risks are assessed and managed appropriately.

8.1 The registered person must ensure that there is a comprehensive written risk management policy and procedures, which cover:
- the identification and assessment of risks throughout the clinic
- the precautions in place control the risks identified
- health and safety
- infection control
- decontamination
- arrangements for the identification, recording, analysing and learning from adverse health events or near misses
- arrangements for responding to emergencies
- protection of vulnerable children and adults, including protection from abuse.

8.2 Arrangements must be in place for dealing with ‘alert letters’ in accordance with Department of Health and Social Care guidance and directions.

8.3 Arrangements must be in place for dealing effectively with ‘hazard notices’ when these are received.

8.4 There must be a written procedure setting out the responsibilities for informing the DHSC and national professional bodies such as the GMC about staff who have been suspended on clinical or professional grounds, or practitioners whose practising privileges have been suspended, restricted or withdrawn on professional or clinical grounds.

8.5 A named member of staff must be identified to receive information from the Medical Devices Agency, and report relevant matters to the Agency (including failure of, and accidents in connection with, medical devices).

8.6 A named member of staff must be identified to receive information from the Medicines Control Agency, and report relevant matters to the Agency.
## Standard 9 - Medicines Management

**OUTCOME**

Measures must be in place to ensure the safe management and secure handling of medicines.

9.1 Medicines must be handled according to the requirements of the Medicines Act 2003 and the Misuse of Drugs Act 1976; and with nursing staff following the *NMC Standards for Medicines Management (2010)* and pharmacists their professional Code of Ethics.

9.2 There must be a written medicines policy and procedure, accessible to staff, covering all aspects of medicines systems and medical gases in the clinic, which covers:

- ordering, procurement, receipt, storage, administration and disposal of medicines
- the action to be taken in case of adverse reactions
- error reporting.

9.3 The medicines required for resuscitation or other medical emergency must be accessible and in suitable packaging.

9.4 All medicine administered to a service recipient must be under direction from a suitably qualified medical practitioner and recorded on a drug administration chart.

9.5 There must be a written policy for the steps to be followed in the exceptional circumstances where a medicine is administered without a written direction, for example, a life threatening situation.

9.6 All medicine doses must be prepared immediately prior to their administration from the container in which they are dispensed.

9.7 Medicines prescribed and labelled received against a prescription for named service recipients must not be used for any other person.

9.8 Information must be given to service recipients about the use, benefits and potential harms of medication prescribed.

9.9 The clinic must have access to up-to-date, relevant reference sources, for example the British National Formulary, the Summary of Product Characteristics for every product used and access to evaluated information about medicines.

9.10 Medicines must be used as specified in the Summary of Product Characteristics, unless there is a body of evaluated evidence to support any use outside this licence. In this case service recipients must be informed that the medicine is used outside the Summary of Product Characteristics.

9.11 When clinical trials take place they must be undertaken in accordance with relevant legislation and best practice guidelines and with local research ethics committee approval.

9.12 When service recipient group directions must be used they comply with Department of Health/Medicines Control Agency guidance.

9.13 A record must be kept of ordering, receipt, supply, administration and disposal of all medicines dressings and medical gases.
9.14 Lockable storage must be provided for:

- controlled drugs in accordance with the Misuse of Drugs (Safe Custody) Regulations 1973
- medicines for external use
- medicines for internal use
- medicines requiring cold storage
- diagnostic reagents (other than test strips)
- flammable substances.

9.15 The storage of medical gases must be in accordance with guidance set out in Health Equipment Information No 163, 2/87.

9.16 The keys of all cupboards used for the storage of medicines must be held securely, including spare keys.

9.17 Medicines requiring cold storage must be not kept in refrigerators used for domestic purposes but in a separate, designated refrigerator.

9.18 There must be daily monitoring of the temperature of the refrigerator used to store medicinal products, checks must be recorded and signed. A written procedure must be in place outlining the action to be taken if the temperature is outside the normal range.

9.19 Controlled drugs must be handled in compliance with the requirements of the Misuse of Drugs Act and its regulations.

9.20 A clinic that holds stocks of controlled drugs listed in Schedule 2 of the Misuse of Drugs Act must have a Home Office licence.

9.21 Where a pharmacist is employed, the purchase and issue of controlled drugs must be under their direct supervision and includes authorising orders to suppliers.

9.22 Where no pharmacist is employed, a medical practitioner or a dentist must countersign orders signed by the registered nurse for a controlled drug.

9.23 In the case of Schedule 2 controlled drugs (except those in Schedules 4 and 5) an appropriate record must kept of the invoices, receipt, administration and disposal of the drugs in accordance with the Misuse of Drugs Regulations 1985.

9.24 Controlled drugs must be destroyed in the presence of an authorised person (that is a police officer, an inspector of the Home Office Drugs Branch or an inspector of the Royal Pharmaceutical Society of Great Britain), or the person to whom this function has been formally delegated, such as the registered manager or registered nurse of the clinic.
Standard 10 - Record Management

**OUTCOME**
All records must be managed, handled and stored appropriately in line with confidentiality and data protection principles

10.1 All entries made in records must be dated, timed and signed.
10.2 All entries in records must be legible.
10.3 Any alterations or additions must be dated, timed and signed, and made in such a way that the original entry can still be read.
10.4 All health care professionals must record all treatment given and recommendations made in the service recipient’s health record.
10.5 A summary of the health record must be sent to the person’s GP within a locally agreed timescale, but which is no more than four weeks.
10.6 When the referral is not from the service recipient’s GP, the service recipient must be asked to formally sign a form to give or refuse consent for sending details of the treatment provided (the consultant’s discharge letter) to their GP.
10.7 If the service recipient does not give consent for details to be sent to their GP, a summary of the treatment provided must be given direct to the service recipient so that they have it for future reference, to pass on to the GP.
10.8 Storage of records must be managed effectively and securely and in accordance with requirements of applicable legislation.

Standard 11 - Research

**OUTCOME**
Any research conducted at the clinic must be carried out with appropriate consent and authorisation in line with published guidance on the conduct of research projects.

11.1 There must be a written policy which states whether or not research is carried out in the clinic.
11.2 Where the policy states that research is carried out within the clinic, there must be written procedures that set out the requirements to be met concerning research projects.
11.3 All clinical research projects must be conducted in accordance with the Department of Health research governance framework.
11.4 Any new interventional procedures to be carried out in the establishment are must be referred to NICE.
11.5 All clinical research projects must be approved by a Research Ethics Committee.
11.6 There must be documented agreements in place for the allocation of responsibilities between all parties involved.
11.7 The lead professional for each research project must be documented.

11.8 The responsibilities of the lead professional must include:
   - the management of the research project
   - the monitoring of progress on the project.

11.9 There must be documented agreements in place between the establishment/agency and their personnel and between the establishment/agency and funders about ownership, exploitation and income from any intellectual property that may arise from research conducted on their premises.

11.10 Records must be kept of all research projects, including information about the service recipients involved, or service recipients whose data or tissue has been used in the project, for 15 years after the conclusion of the treatment.

11.11 Lawful consent or authorisation must be obtained for the participation of any service recipient in a research project.

11.12 The registered person must ensure that all research projects undertaken are appropriate for the organisation to be involved in and are properly managed.
This document can be provided in other formats

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